S. HRG. 99-499

PROCESS PATENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON
PATENTS, COPYRIGHTS AND TRADEMARKS

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

S. 1543

A BILL TO PROTECT PATENT OWNERS FROM IMPORTATION INTO THE UNITED STATES OF GOODS MADE OVERSEAS BY USE OF A UNITED STATES PATENTED PROCESS

OCTOBER 23, 1985

Serial No. J-99-66

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE
55-522 O WASHINGTON : 1986

S521-41.

COMMITTEE ON THE JUDICIARY

STROM THURMOND, South Carolina, *Chairman*

CHARLES McC. MATHIAS, Jr., Maryland	JOSEPH R. BIDEN, Jr., Delaware
PAUL LAXALT, Nevada	EDWARD M. KENNEDY, Massachusetts
ORRIN G. HATCH, Utah	ROBERT C. BYRD, West Virginia
ALAN K. SIMPSON, Wyoming	HOWARD M. METZENBAUM, Ohio
JOHN P. EAST, North Carolina	DENNIS DeCONCINI, Arizona
CHARLES E. GRASSLEY, Iowa	PATRICK J. LEAHY, Vermont
JEREMIAH DENTON, Alabama	HOWELL HEFLIN, Alabama
ARLEN SPECTER, Pennsylvania	PAUL SIMON, Illinois
MITCH McCONNELL, Kentucky	

DENNIS W. SHEDD, *Chief Counsel and Staff Director*
DIANA L. WATERMAN, *General Counsel*
DEBORAH G. BERNSTEIN, *Chief Clerk*
MARK H. GITENSTEIN, *Minority Chief Counsel*

SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS

CHARLES McC. MATHIAS, Jr., Maryland, *Chairman*

PAUL LAXALT, Nevada	PATRICK J. LEAHY, Vermont
ORRIN G. HATCH, Utah	HOWARD M. METZENBAUM, Ohio
ALAN K. SIMPSON, Wyoming	DENNIS DeCONCINI, Arizona

STEVEN J. METALITZ, *Chief Counsel and Staff Director*
PAMELA S. BATSTONE, *Chief Clerk*

CONTENTS

STATEMENTS OF COMMITTEE MEMBERS

	Page
Mathias, Hon. Charles McC., Jr., a U.S. Senator from the State of Maryland, chairman, Subcommittee on Patents, Copyrights and Trademarks	1
Leahy, Hon. Patrick J., a U.S. Senator from the State of Vermont	44

PROPOSED LEGISLATION

S. 1543, a bill to protect patent owners from importation into the United States of goods made overseas by use of a United States patented process	3

CHRONOLOGICAL LIST OF WITNESSES

Lautenberg, Hon. Frank R., a U.S. Senator from the State of New Jersey	6
Quigg, Hon. Donald J., Commissioner, Patent and Trademark Office, Washington, DC; Hon. Douglas H. Ginsburg, Assistant Attorney General, Antitrust Division, Department of Justice, Washington, DC; and Harvey E. Bale, Jr., Esq., Assistant U.S. Trade Representative for Trade Policy and Analysis, Washington, DC	8
Banner, Donald W., president, Intellectual Property Owners, Inc., Washington, DC; Gerald J. Mossinghoff, president, Pharmaceutical Manufacturers Association, Washington, DC; Dr. Marc J. Ostro, vice chairman and chief service officer, the Liposome Co., Princeton, NJ; Roy H. Massengill, Esq., general patent counsel, Allied-Signal, Morristown, NJ; and Nolan Hancock, Esq., on behalf of Oil, Chemical & Atomic Workers International Union, Washington, DC	48
Haddad, William F., chairman, Generic Pharmaceutical Industry Association, New York, NY; Alfred B. Engelberg, Esq., patent counsel, Generic Pharmaceutical Industry Association, New York, NY; and Nancy L. Buc, Esq., counsel, National Association of Chain Drug Stores, Alexandria, VA	97
Fryer, Prof. William T., III, University of Baltimore School of Law, Baltimore, MD, and Thomas F. Smegal, Jr., president, American Intellectual Property Law Association, Arlington, VA	153

ALPHABETICAL LIST AND MATERIAL SUBMITTED

Banner, Donald W.:	
Testimony	48
Prepared statement	50
List of supporters of process patent legislation	58
Replies by Intellectual Property Owners, Inc., to questions from Senator Mathias	61
Bale, Harvey E., Jr.:	
Testimony	34
Prepared statement	35
Letter to Hon. Charles McC. Mathias, Jr., January 29, 1986	40
Buc, Nancy L.:	
Testimony	135
Prepared statement	137
Letter to Hon. Charles McC. Mathias, Jr., December 9, 1985	142
Enclosure: Responses to written questions of Senator Mathias	143
Engelberg, Alfred B.:	
Testimony	106
Prepared statement	109

ALPHABETICAL LIST AND MATERIAL SUBMITTED—Continued

Page

Engelberg, Alfred B.—Continued
GPIA responses to written questions of Senator Mathias 119
"Laws and Practice," article by Kyoji Murayama, from AIPPI Journal, December 1984 123

Fryer, William T., III:
Testimony 153
Prepared statement 155
Letter to Hon. Charles McC. Mathias, Jr., October 29, 1985 159
Enclosures:
Sinclair Oil Corp. case, 280 A.2d 717 162
Hycor Corp. case, 222 USPQ 553 167
E.I. du Pont de Nemours Powder Co. case, 244 U.S. 100 176
Ginsburg, Douglas H.:
Testimony 24
Prepared statement 26
Letter to Hon. Charles McC. Mathias, Jr., March 7, 1986 32
Haddad, William F.:
Testimony 97
Prepared statement 101
Hancock, Nolan W.:
Testimony 88
Prepared statement 90
Lautenberg, Senator Frank R.: Testimony 6
Massengill, Roy H.:
Testimony 79
Prepared statement 81
Responses to written questions of Senator Mathias 85
Mossinghoff, Gerald G.:
Testimony 64
Prepared statement 65
Responses by the Pharmaceutical Association to questions from Senator Mathias 68
Ostro, Marc J.:
Testimony 72
Prepared statement 74
Responses to written questions of Senator Mathias 77
Quigg, Donald J.:
Testimony 8
Prepared statement 10
Chart of process patent protection in group B countries, along with examples of foreign laws in this area 16
Responses to written questions of Senator Mathias 20
Smegal, Thomas F., Jr.:
Testimony 178
Prepared statement 180
Letter to Hon. Charles McC. Mathias, Jr., December 6, 1985 184

APPENDIX

ADDITIONAL SUBMISSIONS FOR THE RECORD

Testimony of the New York Patent, Trademark and Copyright Law Association on S. 1543, submitted by John O. Tramontine, president 191
"The Non-Obvious Reasons Why S. 1543 Should Be Enacted," testimony in support of S. 1543, submitted by Alfred L. Michaelsen, general patent counsel, Corning Glass Works, Corning, NY 196
"U.S. Process Patent Protection: The Need for Extraterritorial Effect—The Biotechnology Industry as a Case Study," by Kenneth J. Woolcott, Spring 1985 208
Statement of the American Textile Manufacturers Institute 230

CORRESPONDENCE

Page

Letters to Hon. Charles McC. Mathias, Jr., chairman, Subcommittee on Patents, Copyrights and Trademarks, from:
W.L. Keefauver, vice president and general counsel, AT&T, October 21, 1985 231
Lee Hamilton, senior vice president, NAM, October 23, 1985 233
W.S. Thompson, manager, patent department, Caterpillar Tractor Co., November 14, 1985 236
Enclosure: Statement for the record by Caterpillar Tractor Co 237
Richard G. Waterman, general patent counsel, The Dow Chemical Co., November 14, 1985 239
James W. Leslie, vice president, URI, November 15, 1985 240
Robert C. Sullivan, director, patent department, Stauffer Chemical Co., November 18, 1985 241
Leroy G. Sinn, attorney at law, consultant, Intellectual Property, November 19, 1985 245
David A. Litvin, assistant director, Federal Government Affairs, the Standard Oil Co., November 20, 1985 246
Enclosure: Testimony of Johnathan W. Hinton, vice president and general manager, Structural Ceramic Division, Sohio Engineered Materials Co., before the Subcommittee on Economic Goals and Intergovernmental Policy of the Joint Economic Committee, on "The Case of Japan: Barriers to U.S. Exports," August 22, 1985 247
Ellis K. Fields, office of the president, American Chemical Society, November 21, 1985 256
John O. Mingle, Esq., patent counsel, executive vice president, KSU, November 21, 1985 258
Birgit E. Morris, president, New Jersey Patent Law Association, November 21, 1985 259
Albert D. Bourland, vice president, congressional relations, Chamber of Commerce of the United States of America, November 22, 1985 261
R.K. Pitler, senior vice president and technical director, Allegheny Ludlum Steel Corp., November 25, 1985 262
Jack R. Halvorsen, president, the Patent Law Association of Chicago, November 26, 1985 264
A. Robert Stevenson, K mart Corp., December 23, 1985 265
J. Jancin, Jr., section chairman, American Bar Association, March 10, 1986 266
William H. Neukom, secretary, American Bar Association, March 15, 1986 269
Attachment: Resolution adopted February 10–11, 1986 270
Letter to Hon. Strom Thurmond, chairman, Senate Committee on the Judiciary, from George Schwartz, executive director, NAPM, November 12, 1985 234
Letter to Hon. Frank R. Lautenberg and Hon. Charles McC. Mathias, Jr., from A. Sidney Alpert, Esq., president, University Patents, Inc., November 18, 1985 242
Enclosure: Proposed modification to 35 U.S.C. 283 244

PROCESS PATENTS

WEDNESDAY, OCTOBER 23, 1985

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS,
Washington, DC.

The subcommittee convened, pursuant to notice, at 9:46 a.m., in room SD-628, Dirksen Senate Office Building, Hon. Charles McC. Mathias, Jr. (chairman of the subcommittee), presiding.

Also present: Senator Leahy.

Staff present: Diana Waterman, general counsel; John Podesta, minority chief counsel; Steven J. Metalitz, staff director; Charles W. Borden and Sharon M. Donovan, professional staff; Pamela S. Batstone, chief clerk; Beverly E. McKittrick, counsel; Timothy Rieser (Senator Leahy's staff); Jacqueline Hightower (Senator DeConcini's staff).

OPENING STATEMENT OF HON. CHARLES McC. MATHIAS, JR., A U.S. SENATOR FROM THE STATE OF MARYLAND, CHAIRMAN, SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS

Senator MATHIAS. The subcommittee will come to order.

The subcommittee meets this morning to take testimony with respect to the Process Patent Amendments, Senate bill 1543, which was introduced by Senator Lautenberg and myself at the end of July. This is not novel legislation. In fact, similar legislation actually passed in the other body and was approved by the Senate Judiciary Committee last year, but it came so late in the session that it was sidetracked in the final rush for adjournment.

The bill aims to strengthen the patent system by eliminating a loophole that affects products that are manufactured in other countries, but manufactured by the use of a process patented in the United States.

Under current law, these products are legally imported into the United States and are then either used or sold in competition with products made in the United States by the holder of the U.S. patent, or someone licensed by him.

The net effect of this situation is to exacerbate the trade deficit and to cost American jobs because the work that is being done in other countries is not being done here.

Senate bill 1543 would attempt to narrow this loophole, hopefully, to close it by prohibiting the importation or the use or the sale in this country of products made abroad by a process patented in the United States.

It is interesting to note that President Reagan included process patent reform in his recently announced package of trade initiatives. Prior to that, the President's Commission on Industrial Competitiveness strongly recommended that the Congress enact process patent reform.

We are going to have the administration position today presented by the Commissioner of Patents and Trademarks, so I will not expound on that any further. We will also have representatives from the Department of Justice and the Office of the U.S. Trade Negotiator. We will hear from representatives of the chemical, pharmaceutical, and biotechnology industries—all of which have been adversely affected by this process patent loophole. And we will explore the concerns of the retailers and of the generic pharmaceutical industry, and discuss with these witnesses some of the precautions that have been included in the bill to make sure that the other end of this proposition, that enhanced protection for patented processes, does not cut off supplies to any domestic business or adversely affect consumers.

And we will hear from legal experts who have studied and practiced patent law and who will be able to give us some estimate of the impact of this proposal.

[A copy of S. 1543 follows:]

II

99TH CONGRESS
1ST SESSION

S. 1543

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

IN THE SENATE OF THE UNITED STATES

JULY 31 (legislative day, JULY 16), 1985

Mr. MATHIAS (for himself, Mr. LAUTENBERG, Mr. LAXALT, Mr. DECONCINI, Mr. SPECTER, Mr. DENTON, and Mr. DIXON) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

---

A BILL

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Process Patent Amendment of 1985".

SEC. 2. (a) Section 154 of title 35, United States Code, is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling products produced thereby

throughout, or importing products produced thereby into, the United States,".

(b) Section 271 of title 35, United States Code, is amended by—

(1) inserting "(1)" after "(a)";

(2) adding at the end of subsection (a), the following:

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by such process infringes the patent.".

(c) Section 287 of title 35, United States Code, is amended by—

(1) inserting "(a)" before "Patentees,"; and

(2) adding at the end thereof the following new subsection:

"(b) No damages shall be recovered by the patentee for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process except on proof that such infringer knew of or was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such knowledge or notice. Filing of an action for infringement shall constitute such notice.".

SEC. 3. This Act shall apply only to products produced or imported after the date of enactment. This Act shall not abridge or affect the right of any persons or their successors in business to continue to use, sell or import any specific product already in substantial and continuous commercial production on July 31, 1985, or for which substantial preparation for production was made before that date, to the extent equitable for the protection of investments made or business commenced before that date. This Act shall not deprive a patent owner of any other remedies available under 15 U.S.C. 271, 19 U.S.C. 1337, or any other statutory provision.

SEC. 4. For five years after the date of enactment, the Department of Commerce shall report annually to Congress on the effect of this Act on the importation of ingredients to be used for manufacturing products in the United States in those domestic industries that submit formal complaints to the Department alleging that their legitimate sources of supply have been adversely affected.

O

Senator MATHIAS. I now want to welcome my colleague and cosponsor, the Senator from New Jersey, Mr. Lautenberg, who was very helpful in efforts to pass this provision last year; who is not only the principal cosponsor of the bill this year, but who has come to the Senate from real life recently enough that he understands the practical aspects.

Senator Lautenberg.

STATEMENT OF HON. FRANK R. LAUTENBERG, A U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. I thank you, Mr. Chairman.

I am pleased to appear before your subcommittee this morning. I am here to state my strong support for the Process Patent Amendment of 1985. This bill will help protect American technology and spur investment in innovation.

America's comparative advantage is its technology. We are leaders in the search for new ideas, but we are not alone in that search. To win the race for innovation, to enjoy the fruits of victory, we must protect intellectual property like patents. They reserve to the inventor a chance to exploit his invention to the exclusion of others.

Without patent protection, people are free to steal an invention and avoid the risks of research, avoid the frustrating failures that precede success, but reap the harvest that the inventor sowed.

The legislation that I have had the pleasure of fashioning with the chairman, the legislation before the subcommittee today, would close a major gap in U.S. patent law, one that deals with patents of processes.

There are two kinds of patents—one, of a product, the other, of a process or a method by which a product is made.

Now, what is the loophole our bill is going to address? Current law bars the unauthorized manufacture, use, or sale of a patent in the United States. "In the United States" are the key words. Where a product patent is at stake and the product is copied abroad, infringement occurs when the product is actually used or sold in the United States. Where a process is at stake, and the U.S. process is copied abroad, there is no infringement of the process patent even if the product made by the process is sold or used in the United States.

So our current patent law does not reach the foreign pirating of most of our most innovative processes even when the products are shipped back to the United States. Our bill would change that. It would make it a violation of U.S. patent law to import into, or to use or sell in the United States, a product made overseas using without permission a U.S.-patented process.

Japan, Britain, West Germany, and France already have such protection for their inventors. Our legislation would bring American law into line.

I want to emphasize that this, as you have stated, Mr. Chairman, is a jobs bill. The International Trade Commission estimated, back in 1982, that infringement of U.S. intellectual property costs Americans jobs—131,000 jobs in just 5 selected industrial sectors. And it

costs sales to American business—$5.5 billion in annual sales. Since 1982, the problem has gotten worse.

Today, process patent holders have just one remedy. They can go to the ITC. The ITC can exclude infringing products, but it cannot compensate for lost earnings, and earnings are what pays off R&D costs. There are other hurdles to getting ITC relief, some of which would be removed by a separate bill that I have introduced. But even so, the ITC remedy is just no substitute for patent law reform.

Process patent reform was a key proposal of the Young Commission on Industrial Competitiveness established by the President. Strengthening intellectual property rights was a major prescription for ensuring economic competitiveness.

Companies in my State rank third among the States in patents granted last year. New Jersey ranks third, as well, in patents per capita. We are a very inventive people. Billions are spent in research and development. Effective patent protection is critical if we are to maintain that activity. It is important for giant firms like Allied-Signal, and it is important for new companies, startups, like those in the biotech industry, like Liposome, and it is important to the workers represented by the Oil, Chemical & Atomic Workers Union, and others.

I want to thank you, Mr. Chairman, for inviting the witnesses here from New Jersey and for providing me an opportunity to come before the subcommittee.

The chairman has made a major contribution in undertaking this initiative, and I commend you for it. It has been a pleasure working with the chairman on this issue, and I hope that our bill is going to be enacted in the 99th Congress.

Senator MATHIAS. Well, I share that hope, Senator Lautenberg, and I think we have some reason to hope because of the interest that has been expressed in the Congress as well as in the administration. And I know that you would share with me further the desire to address any problem which may result to consumers or to other parts of the industry, because now is the time to address those concerns. And I think this hearing today will give us that opportunity.

Thank you very much.

Senator LAUTENBERG. Thank you.

Senator MATHIAS. Our next witnesses will be the Honorable Donald Quigg, the Commissioner of the Patent and Trademark Office; the Honorable Douglas H. Ginsburg, Assistant Attorney General of the Antitrust Division; and Mr. Harvey Bale, Assistant U.S. Trade Representative for Trade and Policy Analysis.

We will ask them to come together to the table. It is a great pleasure to have all of them here. Commissioner Quigg has been a frequent visitor to this committee, but he appears today for the first time since his confirmation. I am happy to congratulate him on that.

If you have no preference as to how you will speak, we will go down the table and begin with Commissioner Quigg.

STATEMENT OF A PANEL, CONSISTING OF HON. DONALD J. QUIGG, COMMISSIONER, PATENT AND TRADEMARK OFFICE, WASHINGTON, DC; HON. DOUGLAS H. GINSBURG, ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION, DEPARTMENT OF JUSTICE, WASHINGTON, DC; AND HARVEY E. BALE, JR., ESQ., ASSISTANT U.S. TRADE REPRESENTATIVE FOR TRADE POLICY AND ANALYSIS, WASHINGTON, DC

Mr. QUIGG. Thank you, Mr. Chairman.

I welcome this opportunity to testify on S. 1543, the Process Patent Amendment of 1985. With your permission, I would like to summarize my remarks and present a written statement for the record.

Senator MATHIAS. Your written statement will be included in full in the record.

Mr. QUIGG. Thank you.

By amending title 35, United States Code, to extend the exclusive rights of the holder of a process patent to products made by that process, S. 1543 would give U.S. process patent holders rights which are already available under the patent laws of most of our trading partners.

Under U.S. law, a process patent holder can prevent use of the patented process to manufacture in the United States but cannot prevent use of the process to manufacture abroad or prevent the subsequent use or sale in the United States of these foreign-made products.

As you will notice from the chart attached to my written statement, most of the developed market economy countries, or group B, as well as the European Patent Convention, protect process patent holders against the importation, use, or sale of the direct products of a patented process. About one-half of those countries make importation an infringement, and approximately one-third also provide a presumption in favor of the process patentee, at least where the process is for a new product. We believe it would be beneficial for U.S. law to give equal protection.

Enforcing a patent against an infringer is a substantial undertaking. Without discovery procedures such as are available in the United States, it will be very difficult for a U.S. patent holder to enforce a process patent against a foreign manufacturer who is not subject to service of process in the United States and does not willingly cooperate with the patentee.

A rebuttable presumption should provide that a product which could have been made by the patented process was, in fact, made by that process. This shifts the burden of proof in an infringement suit to the defendant, who should be in a much better position to establish exactly how the product in question was actually made. To obtain the benefit of this presumption, the patentee should be required to demonstrate a substantial likelihood that the product was produced by the patented process, and that a reasonable but unsuccessful effort was made to determine that the process was actually used in the production of the product.

A patentee could establish a substantial likelihood, for example, by showing that the patented process was the only known method, or the only commercially practical method, for producing the prod-

uct, or that physical evidence, such as the exact chemical composition of the product, indicates the use of the patented process. A reasonable effort would be satisfied through the discovery procedures in the United States or, for a foreign manufacturer, by some reasonable step such as writing to the manufacturer. The reasonableness of the effort would depend on the facts of the case but should generally eliminate the need for such measures as letters rogatory or suits in a foreign country.

We also believe that S. 1543 should be amended to clarify that it applies only to products directly produced by the patented process. This would lay to rest arguments that, for example, a product resulting from a series of processes would be covered by a process patent for an intermediate step. The legislative history of the bill should reflect that the provisions of this legislation could not be circumvented by adding immaterial or trivial steps to the process. Identical products made by other processes would not be affected by this act and whether a process was infringed would be judged by the usual principles of patent law.

Mr. Chairman, S. 1543 would provide needed protection for U.S. process patent holders by bringing our law into conformity with those of our trading partners. We urge its enactment.

Thank you.

Senator MATHIAS. Thank you very much, Commissioner.

[Mr. Quigg's submissions for the record follow:]

PREPARED STATEMENT OF DONALD J. QUIGG

SUMMARY

S. 1543, the "Process Patent Amendment of 1985", would improve the U.S. patent law by amending Title 35, United States Code, to extend the exclusive rights of the holder of a process patent to products made by the patented process. This would bring our law into conformity with the laws of our major trading partners by giving the holder of a process patent the right to stop the importation, use or sale within the United States of a product made abroad by a process patented in the United States.

Under present United States patent law, a U.S. manufacturer who uses the patented process would infringe, while a foreign manufacturer using the process abroad would not. The subsequent use or sale of the resulting products may effectively destroy the value of the U.S. process patent and perhaps the patent holder's ability to recover an initial R&D investment. This particularly poses a problem for process patent holders making products which are themselves unpatentable. Failure to remedy this problem exacerbates our trade problems.

Enforcing a patent against an infringer is a substantial undertaking. We believe that it would be desirable to establish a rebuttable presumption that a product which could have been made by patented process was in fact made by the patented process. This provision would greatly relieve the burden on domestic industry where a foreign manufacturer is not subject to service of process in the United States. The provision should also require the patentee to demonstrate, on the basis of available evidence, that a substantial likelihood exists that the product was produced by the patented process and, further, that a reasonable but unsuccessful effort was made to determine that the process was actually used in the production of the product. We also suggest that S. 1543 be amended to clarify that it applies only to products "directly" produced by the patented process. These changes are consistent with the laws of other countries on this subject, as well as with the European Patent Convention. The legislative history of the bill should also reflect that the provisions of this legislation could not be circumvented by adding to the process immaterial steps which are trivial to the process as a whole. Identical products made by other processes would not be affected.

The Administration strongly supports S. 1543. It would strengthen the rights of U.S. process patent holders by providing them the protection available under the laws of our trading partners. Our industry needs this protection. We urge the bill's enactment.

* * *

Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to testify on S. 1543, the "Process Patent Amendment of 1985". This bill would amend Title 35, United States Code, to extend the exclusive rights of the holder of a process patent to products made by the patented process. Unlike the laws of our major trading partners, U.S. patent law does not give the holder of a process patent the right to stop the importation,

use or sale within the United States of a product made abroad by a process patented in the United States.

The Administration strongly supports S. 1543, which would significantly improve the patent law affecting process patents. Under United States law, a patent is infringed if the patented invention is made, used, or sold in the United States. Making, using, or selling the invention outside the United States does not constitute infringement, nor does the mere importation of the invention. Where the patented invention is a product, or tangible article, a foreign competitor cannot avoid liability to the patent holder by manufacturing the product overseas and importing it for the United States market since use or sale of the product in the United States would still constitute infringement, and the patent holder could obtain damages or an injunction based on this use or sale.

Where the patent claims only a process or method, however, only the use of the process in the United States constitutes infringement. Use of the process outside the United States will not infringe the U.S. patent, nor will use or sale of products made by the patented process. Thus, a U.S. manufacturer who uses the patented process would infringe, while a foreign manufacturer would not. When the chief commercial value of the process comes from the use or sale of the resulting product, sale of the foreign-made products may effectively destroy the value of the U.S. process patent and perhaps the patent holder's ability to recover an initial R&D investment.

This situation allows substantial problems to arise for process patent holders making products which are themselves unpatentable. A significant effort of the emerging biotechnology industry is directed toward new ways to produce naturally occurring substances such as insulin or interferon. Since naturally occurring substances are not patentable under the laws of the United States or most countries, failure to remedy this problem now plants the seeds for trade problems in yet another industry.

This leaves the owner of a United States process patent with very limited rights with respect to products made from the process. The only remedy available to a process patentee with respect to a product made by the process is under Sections 337 and 337a of the Tariff Act of 1930, as amended (19 USC 1337 and 1337a). Under Section 337, the patent owner may petition the International Trade Commission (ITC) to determine that the importation of the products of a patented process for use, sale or exchange constitutes an unfair practice in import trade and to exclude the product from entry. Although ITC procedures can be simpler and faster than litigation in United States district court, this remedy requires the patentee to establish that the product was made by a process patented in the United States and that the importation will damage an efficiently and effectively operated domestic industry, or prevent the establishment of such an industry, or will restrain or monopolize trade in the United States. If the International Trade Commission finds a violation, it must publish its findings in the Federal Register and transmit a copy to the President, who can disapprove the determination at any time within a sixty-day period.

When the petitioner is successful, the ITC will exclude the goods from entry. If the goods have already entered the United States, the ITC can issue a cease and desist order against a particular firm. Cease and desist orders against individual firms may not be effective where importers of offending products can easily find alternative channels. Enforcement of exclusion orders by customs officials can also be difficult because of the problem of differentiating products made by the patented process from those produced by another process. If the importation is discovered after the goods have entered commerce, the process patent holder may be left with no remedy since the ITC does not have the authority to award damages. Although ITC proceedings are an important adjunct to enforcement of patent rights, they should not be the sole remedy available to process patent holders against competition from offshore manufacturers.

The only alternative available to a process patentee is to obtain

and enforce patents in as many other countries as possible. This option is unrealistically expensive and largely ineffective because of the impossibility of obtaining adequate protection in all of the countries in which a process might be used. This consideration is particularly important for small and medium-sized businesses who are not doing business abroad and are thus unlikely to seek patent protection for foreign markets. Even if a company is able to afford the legal expenses associated with securing patents around the world, however, patent protection is not available in all the countries in the world. In fact, some countries do not even have patent laws. Even for major markets, this is an expensive alternative. In addition to the substantial costs of securing patents, the patent holder must be prepared to enforce these rights vigorously in many foreign countries. This is realistic only for the largest firms.

Importation, use and sale in the United States of products produced by processes patented in this country severely diminishes the value of such patents. This practice must be effectively countered by changes in the patent laws to protect the legitimate interests of U.S. inventors. Expanding the scope of our laws in this fashion would bring them into conformity with the European Patent Convention and the national laws of many industrialized countries. Mr. Chairman, I have appended to my testimony a chart which summarizes the protection offered to process patent holders in the Group B or developed market economy countries, along with some typical examples of foreign laws in this area. As you will see from the chart, most countries' patent laws are structured so that the direct product of a patented process is also included within the scope of the patent. Nearly one-half of those countries make importation an infringement. S. 1543 is an important step toward providing U.S. industry the protection available to the industry of our trading partners.

Enforcing a patent against an infringer is a substantial undertaking. The patent holder must give notice to the infringer, either directly or by marking the patented product, and if the

infringement continues, the patentee may sue for damages or an injunction in United States District Court.

In the case of a patented process which is carried out in the United States, discovery procedures are available to both foreign and domestic patentees to ascertain whether a product was made by the patented process. However, with respect to products made abroad by processes patented in the United States, the laws of most foreign countries do not provide these discovery procedures. This makes it extremely difficult for a U.S. patent holder to determine the process used to make the product outside the United States. The laws of approximately one-third of the Group B countries provide a presumption in favor of the process patentee in order to overcome that deficiency.

We believe that it would be highly desirable to establish a rebuttable presumption that a product which could have been made by patented process was in fact made by the patented process. This provision would greatly relieve the burden on domestic industry where a foreign manufacturer is not subject to service of process in the United States and where probable infringers do not willingly cooperate with the patentee to assure that infringement has not occurred. The burden of overcoming this presumption should be on the defendant in an infringement suit, since an alleged infringer is in a much better position to establish that a questioned product was made by another process.

We recognize, however, that presumptions should not be casually established. To ensure that an unfair burden is not imposed on importers and distributers of noninfringing products, any provision dealing with this subject should, at a minimum, require the patentee to demonstrate, on the basis of available evidence, that a substantial likelihood exists that the product was produced by the patented process and, further, that a reasonable but unsuccessful effort was made to determine that the process was actually used in the production of the product. To establish a substantial likelihood, for example, a patentee might show that the patented

process was the only known method, or the only commercially practical method, for producing the product, or that physical evidence, such as the exact chemical composition of the product, indicates the use of the patented process. A reasonable effort requirement could easily be satisfied in the United States through our discovery procedures. For a foreign manufacturer the patentee would have to take some reasonable step, such as writing to the manufacturer, to determine how the product was made and to have been unsuccessful in this regard. The reasonableness of the effort would depend on the facts of the case but should generally avoid the need for such measures as letters rogatory or suits in a foreign country.

Absence of a provision of this nature seriously weakens the ability of owners of U.S. process patents to prove infringement. Industrialized countries which are our major trading partners have recognized this difficulty, and many have included presumption provisions in their patent laws. Developing countries, on the other hand, are constantly urged by us to improve their laws to provide strong protection for industrial property. Failure to provide for a presumption in U.S. law, when it is amended to provide increased protection for process patents, could encourage developing countries to follow suit, thereby making it difficult for U.S industry adequately to enforce process patents obtained in those countries.

We also suggest that the language used in S. 1543 should be amended to clarify that it applies only to products "directly" produced by the patented process. This would lay to rest arguments that, for example, a product made by several intermediate processes should be covered by this legislation, when only the first and possibly unimportant process, leading to an intermediate product, was patented. In our opinion, only those products should be covered which are directly made by the patented process. This is consistent with the laws of other countries on this subject, as well as with the European Patent Convention. The legislative history of the bill should, however, reflect that the provisions of this legislation could not be circumvented by adding to the process immaterial steps which are, for example, chemically trivial to the process as a

whole. Identical products made by other processes would not be affected by this Act, but a process would be judged by the usual principles of patent law in determining infringement.

Mr. Chairman, S. 1543 would strengthen the rights of U.S.process patent holders by providing the protection available under the laws of our trading partners. Our industry needs this protection. We urge the bill's enactment.

Process Patent Protection in Group B Countries

Country	Process Patent protects its direct product	Importation constitutes infringement	Presumption in favor of process patentee
Austria[1]	yes		yes[2]
Belgium[1]	yes[3,4]	yes	
Canada	yes[3,4]		yes[2,4]
Cyprus[5]	yes	yes	
Denmark	yes	yes	
Finland	yes	yes	
France[1]	yes	yes	
Federal Republic of Germany[1]	yes		yes[2]
Great Britain[1]	yes	yes	
Greece	yes		yes[2]
Holy See[6]			
Iceland	yes	yes	
Ireland	unclear[3,7]		
Italy	yes		yes[2]
Japan	yes	yes	yes
Liechtenstein[8]	yes		yes
Luxembourg[1,9]	yes[4]		
Monaco[6]			
Netherlands[1]	yes		yes[2]
New Zealand	yes[4]		
Norway	yes	yes	
Portugal	yes	yes	
San Marino[10]	yes		yes[2]
South Africa	yes		yes
Spain	yes	yes[4]	
Sweden[1]	yes	yes	yes[2]
Switzerland[1]	yes		yes
Turkey[9]			
United States of America			

1 EPC member.
2 Applies to new substances only.
3 No clear statutory provision.
4 Apparently applies in at least some situations.
5 Registration in Cyprus of a United Kingdom patent confers the same rights in Cyprus.
6 No patent law.
7 Claims are permitted, but legal issues are apparently unsettled.
8 Liechtenstein and Switzerland constitute a single territory for patent purposes.
9 No copy of the national law was available.
10 Industrial property rights acquired in Italy are valid in San Marino and vice versa.

Denmark

SECTION 3

(1) The exclusive right conferred by a patent shall imply that no one except the proprietor of the patent may without permission exploit the invention:

(i) by making, offering, putting on the market or using a product which is the subject-matter of the patent, or by importing or stocking the product for these purposes;

(ii) by using a process which is the subject-matter of the patent or by offering the process for use in this country if the person offering the process knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent;

(iii) by offering, putting on the market or using a product obtained by a process which is the subject-matter of the patent or by importing or stocking the product for these purposes.

France

CHAPTER THREE.—RIGHTS AND OBLIGATIONS ATTACHED TO THE PATENT

Article 28.—1. The scope of protection conferred by a patent shall be determined by the terms of the claims. The description of the invention and the drawings, however, shall serve to construe the claims.

2. Where a patent relates to a process, the protection conferred by the patent shall extend to the products directly obtained by that process.

Article 29.—A patent confers the right to prohibit any other person, without the consent of the proprietor of the patent:

(a) from making, offering, putting on the market, using, or importing or storing for such purposes the product to which the patent relates;

(b) from using a process to which the patent relates, or, where such other person knows, or where it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within the French territory;

(c) from offering, putting on the market, using, or importing or storing for such purposes the product obtained directly by the process to which the patent relates.

Great Britain

STATUTES, REGULATIONS, & TREATIES

Patents Act 1977

Infringement

60.—(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say—

(*a*) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

(*b*) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;

(*c*) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

§ 5.—No-one may make an occupation of the following without the consent of the patentee:—1. Manufacturing, importing or offering for sale an article which is patented or prepared by a patented method; or 2. Using the patented method.—The following is however, permissible having no regard for a Patent:—a) The use of articles accompanying or connected with means of transport from other countries when these come to this country for limited periods, and b) The continued use of articles arrived by and belonging to means of transport which have been purchased abroad for Icelandic currency or for an Icelandic vessel which has broken down at sea and been repaired abroad.

ITALY

§ 2.—The patent concerning a new industrial method or process confers upon the patentee the exclusive use thereof.

The exclusive use includes also commercializing the product directly obtained by the new industrial method or process. If the product is a new one, every identical product is presumed to have been obtained, unless there is evidence to the contrary, but the method or process which is the subject of the patent.

JAPAN

3. "Working" in respect of an invention in this Law shall mean the following acts:

(1) In an invention of a thing, acts of manufacturing, using, transferring, leasing, exhibiting for the purpose of transfer or lease, or importing the thing;

(2) In an invention of a process, acts of using the process;

(3) In an invention of a process of manufacturing a thing, acts of using, transferring, leasing, exhibiting for the purpose of transfer or lease, or importing the thing produced by the process in addition to those as mentioned in the preceding items.

PORTUGAL

Article 214. A penalty of 500 to 10,000 escudos, to which may be added imprisonment for a period of from one to six months, will be imposed on those who, during the period of legal protection, should prejudice the owner of a patent in the exercise of his right in any of the following ways:

1. Manufacturing, without license from the title holder, the articles or products covered by the patent;

2. Employing, without the said license, the means and processes or using new applications of means and processes forming the subject of the patent;

3. Importing, selling, offering for sale, putting in circulation or concealing, in bad faith, products obtained in any of the ways referred to.

SWEDEN

SECTION 3

The exclusive right conferred by a patent implies, with the exceptions stated below, that no one except the proprietor of the patent may, without the proprietor's consent, use the invention by

(1) making, offering, putting on the market or using a product protected by the patent or importing or possessing such product for these purposes;

(2) using a process which is protected by the patent or, while knowing, or it being obvious from the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use in this country;

(3) offering, putting on the market, or using products made by a process protected by the patent or importing or possessing the product for these purposes.

SWITZERLAND

If the invention concerns a process, the effects of the patent shall extend to the immediate products of the process.

SECTION 67

If the invention concerns a process for the manufacture of a new product, every product of the same composition shall be presumed to have been made by the patented process until proof to the contrary has been adduced.

Subsection 1 shall apply by analogy in the case of a process for the manufacture of a known product if the patentee shows prima facie evidence of infringement of the patent.

WEST GERMANY

PART NINE.—INFRINGEMENT OF PATENT

Article 47

(1) A person who uses an invention contrary to the provisions of Articles 6, 7, and 8 may be sued by the injured party to enjoin such use.

(2) A person making such use intentionally or negligently shall be liable for compensation to the injured party for the damage suffered therefrom. If the infringer has acted with only slight negligence, the court may fix, in lieu of compensation, an indemnity being between the damage to the injured party and the profit which has accrued to the infringer.

(3) In the case of an invention whose subject matter is a process for the production of a new substance, any substance of the same nature shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

Article 6

The effect of the patent shall be such that only the patentee is authorized to produce, put on the market, offer for sale, or use, the subject matter of the invention industrially, commercially or professionally. If the patent has been granted for a process, the effect shall also extend to the products obtained directly by means of such process.

CONVENTION ON THE GRANT OF EUROPEAN PATENTS

(EUROPEAN PATENT CONVENTION)

Done at Munich on October 5, 1973

ARTICLE 64

Rights conferred by a European patent

(1) A European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date of publication of the mention of its grant, in each Contracting State in respect of which it is granted, the same right as would be conferred by a national patent granted in that State.

(2) If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process

(3) Any infringement of a European patent shall be dealt with by national law.

Responses of Donald J. Quigg
to Written Questions of Senator Mathias

Q(1). You testified that S. 1543 should include rebuttable presumptions that shift the burden of proof to defendants in some circumstances. I agree that proof of infringement may be difficult in some cases. But a shift in the burden of proof may present problems too. Don't patentees already have the burden to prove, in ITC cases, importation of products made by patented processes? Does the ITC experience justify your call for presumptions?

A(1). We believe the International Trade Commission (ITC) experience justifies a presumption in favor of the patent holder along the lines we have suggested. The rebuttable presumption we recommend adding to S. 1543 would give process patent holders approximately the same rights in infringement cases in Federal court as in proceedings before the ITC. ITC Rules and the Federal Rules of Civil Procedure (FRCP) each provide for discovery, including production of documents or inspection of a facility, and sanctions for refusal to grant discovery. Where discovery is available, because the alleged infringer either is located in the United States or voluntarily cooperates, we agree that there is no need to shift the burden of proof.

When an alleged infringer is uncooperative, however, practical considerations create important differences in the ability of a Federal court or the ITC to coerce compliance. The in personam jurisdiction of a Federal court limits the effectiveness of sanctions against an uncooperative party. For corporate defendants, the appropriate individuals may be outside the court's jurisdiction. Damages from a default judgment are limited to the case at issue and do not affect future acts of infringement or infringing acts by other parties. Satisfaction of the judgment beyond the assets the corporation owns in the United States is difficult at best, requiring the instigation of a foreign suit and willingness by foreign courts to enforce the U.S. judgment. A court's ability to compel discovery is also limited by the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil and Commercial Matters (Hague Convention). It is unlikely that a court would impose sanctions on a foreign defendant who properly refused discovery based on foreign law pursuant to the Hague Convention. For individuals who are not parties to the case, discovery is relatively simple in the United States under the FRCP but may be impossible where the person is outside the United States.

The in rem jurisdiction of the ITC gives it a greater practical ability to require a respondent to cooperate with discovery. The prospect that an administrative law judge may impose sanctions which will result in loss of the entire U.S. market provides a real incentive for a respondent to cooperate, even when the respondent is outside the jurisdiction of the United States. Since an adverse finding by the ITC may close the U.S. border to all identical products of a manufacturer, even one who is not a party to the proceeding, there is a strong incentive for third parties to cooperate in providing evidence.

A typical sanction against an uncooperative respondent is to prohibit the respondent from presenting evidence on the issue before the ITC. A complainant who has made an adequate case would therefore prevail. A Federal court has the same power,

but because of the strict time limits in ITC cases, administrative law judges impose sanctions more readily than Federal district court judges.

If S. 1543 were enacted with the presumption we recommend, the ITC and Federal court requirements of proof would be nearly identical. They are already essentially the same where all persons with necessary information cooperate with requests for discovery. When they do not cooperate, the presumption would give the patent holder advantages in Federal court that are now available before the ITC. After showing that a reasonable but unsuccessful effort had been made to determine how the product was actually made, the patent holder would then have to show a substantial likelihood that the product was made by the patented process.

This is similar to ITC practice. When sanctions are imposed by the ITC, the complainant may rely on secondary evidence to satisfy the ITC that the product was made by the patented process. We believe that the same kind of evidence which would satisfy the ITC would also be advanced to show a substantial likelihood. For example, chemical analysis of the product or evidence that the patented process was the only known commercial process for producing the product might be adequate to establish a substantial likelihood. The evidence required would depend on the circumstances but should be less than evidence needed for a prima facie case. Otherwise, neither ITC sanctions nor the presumption would assist the patent holder.

Although ITC proceedings have certain limitations, they have been enormously helpful to U.S. patent holders. We believe their success justifies adding a presumption to your bill on process patent infringement.

Q(2). In almost every kind of litigation, the defendant is more likely than the plaintiff to have access to evidence that proves the wrongfulness of his conduct. Yet we don't ordinarily shift the burden of proof in civil litigation; the plaintiff bears the risk of non-persuasion. This is true even in cases involving conduct that occurs in part outside the United States (e.g., an antitrust case against a foreign corporation doing business in the United States). What would make cases brought under this legislation, if enacted, so different?

A(2). We believe it is appropriate to shift the burden of proof to an alleged infringer under this legislation as a matter of public policy. Without compulsory process to discover evidence from the other party, a process patent holder would have little practical ability to enforce the patent against an uncooperative party. When discovery is unavailable, it seems more appropriate to shift the burden of proof and therefore the risk of loss to the party with better means of knowledge. In addition, a presumption would discourage the importation of products made by patented processes by encouraging purchasers to exercise reasonable care to avoid infringement.

An alleged infringer may appear in Federal court either as a defendant, where the patentee brings a civil action for infringement, or as a plantiff, where the alleged infringer brings a declaratory judgment action. The two major issues in infringement cases are whether the alleged infringing product or process is covered by the claims of the patent and whether the claims are valid. The patent holder must show that the claims apply, but invalidity is an affirmative defense which the alleged infringer must assert and prove. By statute the

burden of showing invalidity remains with the party asserting it, and cases indicate that the burden of showing infringement remains with the patentee even as a defendant in a declaratory judgment action.

The presumption we suggest would make manufacture by another process, like patent invalidity, an affirmative defense to a charge of infringement in limited circumstances. This will provide important practical benefits for the process patent holder and would avoid the issue of sanctions against a party who claims the benefit of the Hague Convention.

Also as a matter of policy, a presumption will discourage infringement of U.S. patents by signaling to purchasers the importance of determining the authority of a seller. Purchasers would guard against infringement of process patents just as they do today for product patents. It should be no more burdensome for a purchaser to inquire about patent rights than to ascertain title to avoid purchasing stolen goods, but the existence of the presumption should prompt an inquiry before purchase by a reputable importer or retailer.

We do not believe the presumption we have recommended represents a radical departure from Anglo-American norms. In many circumstances the burden of proof is shifted to the defendant. On determining which party should bear the burden of proof, Wigmore on Evidence states,

> The truth is that there is not and cannot be any one general solvent for all cases. It is merely a question of policy and fairness based on experience in the different situations. Thus, in most actions of tort there are many possible justifying circumstances - self-defense, leave and license, volenti non fit injuria, and the like; but it would be both unfair and contrary to experience to assume that one of them was probably present and to require the plaintiff to disprove the existence of each one of them; so that the plaintiff is put to prove merely the nature of his harm and the defendant's share in causing it; and the other circumstances, which would if they existed, leave him without a claim, are put upon the defendent to prove.

It is true that Congress and the courts have not seen fit to shift the burden of proof in all cases where discovery is difficult because of activities outside the United States. In the example you cite, an antitrust case against a foreign corporation, many of the same facts would favor shifting the burden of proof. An important distinction, however, is antitrust defendants' potential criminal liability on the same facts which give rise to civil liability.

Q(3). In international organizations, the United States is often in the position of encouraging other countries to bring their legal protections for intellectual property up to the level of a consensus of world opinion. Since many industrialized countries now provide protection similar to that contained in S. 1543, what message will we send if we fail to enact this legislation? What effect whould this have on the strength of our position in discussions with other countries that we think need to do better?

A(3). The United States has supported strong protection for intellectual property in various international fora and on a bilateral basis for many years. On occasion we have been the

only nation opposing changes which would weaken international norms.

Among industrialized countries with market economies, the trend is clearly toward greater protection. Many developing countries, on the other hand, have sought through international fora to lower minimum standards of protection and have enacted national laws enabling their industry to utilize valuable intellectual property of the industry of developed nations without adequate remuneration. By contrast, the United States has advocated enacting strong intellectual property laws to encourage investment and the development of indigenous industry.

Generally the United States has had higher standards of intellectual property protection than most countries. This is important if our arguments in favor of increased protection worldwide are to be taken seriously. Otherwise, any weakness in our law will be advanced to justify other nations' weak intellectual property protection.

In this case the United States does not afford its nationals protection which is available in many other countries. It is important to our negotiating role on behalf of U.S. industry that we also lead in the protection we offer. Failure to provide the strongest protection possible tells developing countries that domestic political constraints are an adequate justification for weak intellectual property laws.

Q(4). This question seeks to expand the record on the subject of the historical origin of the different treatment under U.S. laws of process patents. One of the witnesses at the hearing on October 23rd suggested that most developed countries (naming Germany and Japan) 15 to 20 years ago did not have product patent protection on pharmaceuticals and chemicals, so that process patent protection was the only available protection in these industries and it was naturally enforced more broadly with respect to imported products than our laws were.

Do you have any comments on this explanation? Also, if it is accurate, can you also tell us whether the laws in those countries held the purchasers and users as well as the manufacturers liable for products made by a process patented in that country? And if so, when the countries revised their laws to include product patent protection, did they also retain the stronger approach to process patent protection?

A(4). It is correct that Germany and Japan only began to protect chemical products within the last 20 years. The United States, on the other hand, has always offered protection for chemical products, and the United Kingdom has done so for many years.

In 1968 Germany repealed provisions of its nineteenth century patent law prohibiting patents on foods, pharmaceuticals and chemical products as part of a major patent law revision. The fact that many industrialized countries already offered such protection was cited as a reason for the change.

In 1975 Japan amended its patent law to cover chemical compounds, foods and pharmaceuticals, all of which were previously unpatentable. An article on this change in the May 1975 Japan Patents & Trademarks, published by T. Suzuye & Co., Tokyo, gives the following explanation for the change:

> [Japan's] present level of technical development has made

Japan a member of the so-called developed countries, and non-grant of substance patents has resulted in a decline of will to develop new substances -- by research concentrated on mere improvement of the existing methods rather than creation of new substances.

In both cases when these countries amended their laws to include chemical compounds, the revisions did not affect their laws prohibiting the importation, use or sale of products made by the patented process or presumptions in favor of the patentees in those cases.

We think the important point is that when these countries began to protect products, they did not repeal their laws protecting the products of patented processes. Both forms of protection have been in effect in several countries for a number of years.

The provisions of S. 1543 closely resemble those of many countries with strong process patent protection. Typically those laws list importation as an activity which constitutes infringement and include in the definition of the patent right a statement that, if the invention is a process, the patent right extends also to the product produced directly by the process. In other countries, the statutes specify that where the invention is a process, acts of using, selling, or importing the direct product will also be an infringement, language virtually identical to that of S. 1543.

The activities which constitute infringement vary by country. Manufacture, use, sale, and importation are the acts most commonly prohibited. In most countries, purchase alone is not an infringement. However, we are aware of no provisions which excuse infringement of a process patent on the basis that the user, seller, or importer purchased but did not manufacture the direct products.

Senator MATHIAS. Mr. Ginsburg.

STATEMENT OF DOUGLAS H. GINSBURG

Mr. GINSBURG. Thank you, Mr. Chairman.

I am pleased to be here today on behalf of the Department of Justice to speak in support of S. 1543. With the chairman's permission, I will submit my written statement for the record and make a brief oral statement at this time.

Senator MATHIAS. Perhaps I should say as a general proposition that this morning we will direct the reporter to include all written statements in the record, so the witnesses can be advised that their summaries will be entirely appropriate.

Mr. GINSBURG. Thank you, Mr. Chairman.

The Department of Justice strongly supports this legislation, but we do wish to join with the Commissioner in suggesting that certain amendments be made to the bill.

We believe that the bill is nonetheless conceptually and technically sound and that the passage of this sort of legislation is now long overdue.

The present situation which the Commissioner has just described, with respect to the protection of process patents in the

United States, creates an unnecessary and unfortunate disincentive to investment and production in the United States. And it does so at a time where, for several industries that are particularly dependent upon process patent protection, decisions about investment could be substantially affected by the legal regime. The biotechnology industry, of course, comes first to mind. In the last year, as a member of the administration's working group on biotechnology and regulation, I had the opportunity to learn something about that industry and the problems it is facing, and I think as we see that industry beginning to take off and facing substantial competition from other vast industrial countries, the correction of the process patent situation that we now have should be thought of as terribly important to the future of that industry.

Biotechnology is not alone in that respect, and I think it is important that no further industries be given incentives to develop offshore, rather than in the United States, when the technological leadership has originated here, and only the legal regime conducive to investment is lacking.

We do suggest that the bill be amended along the lines discussed by the Commissioner so that if an American patentee is unable, after making reasonable efforts through discovery, to determine whether its patent is in fact being infringed, and if it can show that there is a substantial likelihood that it is being infringed, the burden of proof would shift to the defendant in order to show that the patent is not being infringed. The defendant may be, and typically will be, in a superior position to produce proof on that subject, since it will be at the very least in a contractual relationship, directly or through a chain of contractual relationships, with the original manufacturer.

Second, we would suggest that the legislation be amended in order to put some bounds on the degree to which the importation, use or sale of a product in this country produced with only the remotest reliance on a patented process would be covered by the bill.

We are concerned here about a process patent that might be infringed in, for instance, the extraction of minerals from the earth, those minerals later being used to manufacture materials, which are later embodied in components, which are in turn used in the assembly of the product in question. At some point, it does seem to us that the directness of the relationship between the infringement and the product being imported should be a limitation on the reach of the bill.

Mr. Chairman, with those qualifications, I can only say that we are anxious to see legislation of this sort enacted at the earliest possible time, and we very much appreciate your efforts to do so.

Senator MATHIAS. Thank you very much, Mr. Ginsburg.

[Mr. Ginsburg's submissions for the record follow:]

Prepared Statement of Douglas H. Ginsburg

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to present the Department's views on S. 1543, a bill that would protect the owners of United States process patents from the importation into the United States of goods made overseas by use of their patented processes. The Department strongly supports such legislation. We suggest certain amendments to this bill, which I will mention in a moment, but in general, we think that S. 1543 is conceptually and technically sound, and that passage of such legislation is long overdue. Indeed, on September 23, 1985, the President announced his commitment to work with Congress on legislation to protect intellectual property rights, including trade in articles that infringe U.S. process patents.

Adequate protection for patents and other intellectual property rights is of prime importance to research and development and thus to innovation and productivity. Without such protection, the incentives to engage in such activities are dulled, because others can freely appropriate much of the valuable technology produced thereby. This potential "free rider" problem is the basis for most of our intellectual property laws, including particularly our patent laws.

Because investment in research and development designed to create new processes--ways of creating new products or producing existing products more efficiently by using fewer of society's scarce resources--is so important, our patent laws must adequately protect inventions of this nature.

Unfortunately, present patent law contains a troublesome loophole as far as process patents are concerned--a patentee cannot prevent the use abroad of its patented process and the subsequent importation and sale in the United States of products produced thereby. This loophole does not exist with respect to product patents, and it should be closed for process patents as well.

Under existing law, a patent is infringed only if the patented invention is made, used, or sold in the United States. Where a product patent is involved, a firm cannot avoid infringement by manufacturing the product overseas and then importing it into the United States because the use or sale of the product in the United States would infringe the patent. In the case of a process patent, however, there is no patent law that a patentee can use to stop a firm from practicing the process patent overseas and then selling the product made by that process in the United States. In such a case, technically, no one has made, used, or sold the patented process in the United States.

A patentee has two options to protect its patented process from such use overseas. First, it can seek to obtain a patent in as many overseas countries as possible and then sue for infringement of its foreign patents, in foreign courts, when the process is carried out in those countries. This option is inadequate because it is both expensive and difficult, if not impossible, to obtain adequate protection in all of the countries in which the process might be used.

The other option available to a patentee is to seek relief from the International Trade Commission for violation of 19

U.S.C. § 1337. 1/ Damages are not available to a patentee in a § 1337 proceeding, but the Commission can issue a cease and desist order against a particular firm if it finds that the firm is violating or there is reason to believe that it is violating § 1337. The Commission can also issue an exclusion order that would bar the importation of products made by the patented process if it finds that § 1337 has been violated. These options do not always adequately protect process patentees, however. In order to obtain a cease and desist order or an exclusion order, a patentee must show not only the importation of a product made by its patented process, but also that the effect or tendency of such importation is to destroy or substantially to injure a U.S. industry, or to restrain or monopolize U.S. trade and commerce. Moreover, cease and desist orders against particular firms may not be effective where importation of the offending product can easily find alternative channels. And enforcement of exclusion orders by customs officials can often be problematic because of the difficulty of differentiating products made by patented processes from those that were not. Thus, it can be difficult for a process patentee to obtain effective protection under § 1337 where its patented invention is practiced overseas and the resulting product is sold in the United States.

1/ Section 1337 provides that unfair methods of competition and unfair acts in the importation of articles into the United States, the effect or tendency of which is to destroy or substantially injure an industry efficiently and economically operated in the United States, or to prevent the establishment of such an industry, or to monopolize United States trade and commerce, are unlawful. Section 1337a provides that the importation of a product made under a patented process shall have the same status under § 1337 as the importation of a patented product. Since the case law has established the unauthorized importation of patented products as unfair acts under § 1337, § 1337a in effect means that the unauthorized importation of an unpatented product made by a patented process also may be unfair under § 1337.

S. 1543 would help remedy this situation. It would make the unauthorized importation of products produced abroad by patented processes, as well as the use or sale of such products in the United States, an infringement of the patent, thus enabling process patentees to obtain injunctive and damage relief against such practices under the patent laws. At the same time, it would protect innocent traders in such products by providing that damages for such an infringement may not be recovered from a person who did not actually use the patented process, except on proof that the infringer knew or was notified of the infringement, and continued to infringe thereafter. S. 1543 is thus an effective yet fair measure that should give process patentees important protection, thereby stimulating much needed research and development by American industry.

We do suggest two amendments to S. 1543. First, we think that the bill should establish in certain circumstances a rebuttable presumption that a product that could have been made by use of a patented process was in fact so made in infringement cases based upon importation, use, or sale. This presumption would address the great difficulties a patentee might otherwise have in proving that its patented process was actually used in the manufacture of the product in question where the foreign manufacturer is not subject to service of process in the United States. The burden of overcoming this presumption would be on the defendant in an infringement suit, regardless of whether it is a foreign manufacturer, an importer, or a subsequent purchaser. While the particular defendant might not necessarily have in its possession the means necessary to rebut the presumption, it would be likely to be in a far better position than the patentee to obtain them.

An importer, for example, because of its contractual and business relationship with the foreign manufacturer, would be able to exert influence on such manufacturer to produce the necessary information--at least if it would tend to establish a valid defense. A purchaser from an importer would, in turn, be able to exert a similar influence on that importer, which would be transmitted to the foreign manufacturer.

Presumptions of manufacture by a patented process, however, should not be established casually. An importer or subsequent purchaser might be unable to obtain the information needed to overcome such a presumption, even where the product in question was not in fact made by the patented process. At a minimum, the presumption would subject any party that uses, sells, or imports any product that might have been made by a patented process to increased litigation risks. Indeed, there is some risk that such a presumption might induce frivolous litigation intended only to discourage defendant firms from carrying products that compete with the patentee's product. To minimize these possibilities and avoid unfairness, we believe that two conditions should be satisfied before a product should be presumed to have been made by a patented process.

First, the patentee should demonstrate that there is at least a "substantial likelihood" that the product was made by the patented process. Evidence of this fact could include physical characteristics of the product itself, as well as expert testimony regarding known methods of production at costs that would justify sale of the product at the prices being charged. Exactly how much evidence would be needed in particular situations to satisfy the "substantial likelihood" condition would quickly develop in the case law. A patentee's

burden obviously should be somewhat less than that of proving successfully at trial that a product in question was in fact made by his patented process. On the other hand, a patentee should have to establish more than a slight, even if reasonable, possibility that the product was so made.

Second, the patentee should show that it has made a reasonable effort, but failed, to determine what process in fact was used in the manufacture of the product in question. In other words, the patentee should have to make a good faith effort to prove this key element in its infringment case. A patentee should be expected to undertake discovery as well as other good-faith methods, as the court may deem appropriate. This burden should eliminate frivolous or unsound suits. We will be glad to supply the Subcommittee with draft statutory language that would establish the presumption I have discussed.

We also believe it may be appropriate to clarify that importation, use, or sale only of products directly produced by patented processes is to be considered infringement under the relevant provisions of Title 35 as they would be amended by S. 1543. A contrary interpretation, covering products produced with materials that were themselves produced by patented processes, could expand the scope of the legislation to an undesirable extent. We will be glad to work with the Subcommittee to determine the appropriate scope of protection.

Mr. Chairman, this concludes my prepared remarks. I would be glad to try to answer any questions you or the other members of the Subcommittee may have.

U.S. Department of Justice

Antitrust Division

Office of the Assistant Attorney General

Washington, D.C. 20530

MAR - 7 1986

Honorable Charles McC. Mathias, Jr.
Chairman, Subcommittee on Patents,
Copyrights and Trademarks
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

After the hearing before the Subcommittee on Patents, Copyrights and Trademarks held on S. 1543 on October 23, 1985, you submitted written questions to the witnesses who had testified on behalf of the Administration. The Commissioner of Patents and Trademarks of the Commerce Department, Donald J. Quigg, responded to those questions in a letter dated December 23, 1985. The Department of Justice generally defers to the Patent and Trademark Office in their discussion of the subject areas addressed by your questions. We would, however, like to underscore one aspect of the response to your question 2. That question concerned the Administration's suggestion for an amendment to S. 1543 that would, in certain carefully-defined circumstances, establish a rebuttable presumption in infringement cases based upon importation, use or sale of products produced by patented processes that a product that could have been made by use of a patented process was in fact so made.

We would emphasize that the presumption (or shift in the burden of proof) that the Administration advocates would not be automatic nor would it be casually established. Instead, a presumption of manufacture by a patented process would be available only after two conditions are satisfied by the patentee.

First, the patentee would have to demonstrate on the basis of the evidence that is available that a "substantial likelihood" exists that the product was made by the patented process. Such evidence could include chemical analysis of the product or indications or "marks" on the product itself, as

well as expert testimony regarding known methods of production at costs that would justify sale of the product at the prices being charged. Exactly how much evidence would be needed in particular situations to satisfy the "substantial likelihood" condition would depend on the circumstances. A patentee's burden would be less than that of proving successfully at trial that a product in question was in fact made by the patented process, but would be more than showing a slight possibility that the product was so made.

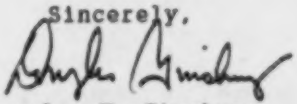
Second, the patentee would have to show that he or she had made a reasonable effort to determine what process was used in the manufacture of the product in question and was unable to do so. These initial efforts would include the use of discovery procedures under the Federal Rules of Civil Procedure or other good-faith methods, such as requesting the information from a manufacturer who may not be subject to U.S. jurisdiction. The reasonableness of the effort would depend on the circumstances.

In sum, we believe that the use of a rebuttable presumption in the carefully-defined circumstances described above would shift the burden of proof in patent infringement cases based on importation, use or sale of a product produced by a patented process only where doing so would produce a just result.

We would be glad to supply the Subcommittee with draft statutory language that would establish the presumption I have discussed.

I appreciate this opportunity to present our views for the record.

Sincerely,



Douglas H. Ginsburg
Assistant Attorney General

Senator MATHIAS. Mr. Bale.

STATEMENT OF HARVEY E. BALE, JR.

Mr. BALE. Senator Mathias, I am going to be brief in the remarks that I have to take about the Process Patent Amendment of 1985. The administration, as my colleagues have indicated, supports the thrust of this bill. I do not want to unduly take the time of the subcommittee to state verbally what is already in my testimony and in the statements of my colleagues.

I am here to provide briefly the trade perspective in consideration by the subcommittee today of this amendment. You mentioned a few minutes ago that the President's statement on international trade addressed and endorsed legislation to amend our laws to address the problem of importation of goods infringing on U.S. process patents.

The administration has been giving increased attention and consideration to the problem of the protection of intellectual property at home and abroad. Our Nation's industrial competitiveness in the production of both goods and services, and the jobs that go along with that production, depend increasingly upon our Nation's ability to reward innovation and know-how.

We must increase the protection of intellectual property worldwide, and process parents are an important component of that, with respect to areas such as biotechnology, pharmaceuticals, electronics, and new types of metals, such as amorphous metals.

I ought to add that I was greatly involved in the preparation of the administration's new thrusts in international trade policy this summer, and we spent a lot of time considering the problem of protection of intellectual property, recognizing that, indeed, we have to make new efforts in this area if we are to preserve our competitiveness and act to reduce our trade deficit.

This is why the administration, in the President's statement, there was an allusion to the process patent amendment. In fact, we had S. 1543 specifically in mind when we were considering legislation over the period of July and August. So this is an important part, we believe, of the President's new trade program. Indeed, if I could make a personal remark, it is a pity the bill is not called "the Process Patent Fair Trade Amendment of 1985," because this is what we think this bill, with certain amendments, in fact, is. So I just want to reiterate and repeat the comments of my colleagues and end my remarks by saying that, in fact, the U.S. Trade Representative and the entire administration, from a trade perspective, as well as the legitimate rights that are at stake here, support very strongly this legislation.

Thank you very much.

[Mr. Bale's submissions for the record follow:]

PREPARED STATEMENT OF HARVEY E. BALE, JR.

I appreciate this opportunity to appear before you in support of S. 1543, the "Process Patent Amendment of 1985".

The Administration is fully committed to the changes in the law it embodies. We feel that the thrust of this bill would significantly improve the ability of Americans to protect their rights and the value of their process patents against foreign misappropriation. This bill is important because it addresses a key issue for our future economic well-being, which is how to better protect our innovative and creative capacity.

Unlike the Agencies' of other witnesses appearing before this Subcommittee, the U.S. Trade Representative's Office has not had a long history of involvement with intellectual property issues.

While this is a relative new issue for us, it has quickly become one of the most important. Over the past two years we have had an ever-increasing number of complaints from U.S. industry about the trade-related problems associated with inadequate intellectual property protection.

Intellectual property protection is rapidly becoming one of the most critical trade and investment issues of this decade and beyond. American industrial and services competitiveness is increasingly dependent on our ability to enjoy the benefits our technological innovations. This requires adequate and effective protection for patents, copyrights and trademarks. Unfortunately too many of our trading partners, both developed and developing countries, do not have adequate laws, fail to enforce them, or, the laws cannot prevent infringement of U.S. intellectual property

rights. Thus, there is a need for vigorous efforts to increase the level of domestic and international protection.

For many countries, especially developing ones, the inadequacy of intellectual property protection often reflects these nation's misguided development strategies. In order to supplement the competitive edge of their products due to lower labor costs, they also adopt policies which attempt to make technology available within their economies at the lowest possible short-term price. Often this mean tolerating the appropriation of foreigners' intellectual property rights, without adequate, prompt and effective compensation.

These policies cause three types of trade problems for Americans. First, U.S. companies can lose sales and the value of investment in the market where the American patent, trademark or copyright is appropriated without authorization. Alternatively, American can lose sales to third markets, when both the unauthorized product, and the legitimate one, are both sold. Finally, and most relevant for the bill you are considering, U.S. companies may lose sales in our own country to imports which are made using American know-how without adequate compensation.

For some time, the Administration has recognized the increasing problems associated with inadequate levels of protection of intellectual property internationally. In 1984, the Administration worked with Congress to develop new initiatives to enhance intellectual property protection through such legislation as the Trade and Tariff Act and the Semiconductor Chip Protection Act. We have also engaged in a series of consultations with foreign countries seeking to improve intellectual property protection, using the recently enacted legislation.

The Administration undertook two additional initiatives very

recently in connection with the President's stepped up efforts in the area of international trade. First, the Administration has accelerated its international efforts both in terms of consultations, and in terms of actions under U.S. unfair trade practices laws. Last week, the President directed Ambassador Yeutter to initiate an investigation of the treatment of intellectual property by the Government of Korea under Section 301 of the Trade Act of 1974. Korea is just one country -- though a very important one -- where foreign holders of patents, copyrights and trademarks do not receive adequate protection. For example, in 1984, according to industry estimates, sales by American pharmaceutical companies in Korea amounted to just $29 million, while sales of their products made through the unauthorized use of U.S. patents accounted for another $70 million. Because these problems are not unique to Korea, other countries may be subject to similar Section 301 investigations by the Administration in the future.

Second, the President stated on September 23, 1985 that the Administration would work with the Congress on legislation to help promote free and fair trade, including legislation to promote intellectual property, such as changes in legislation on process patents.

Currently our laws, unlike those of our major trading partners, give American holders of process patents very limited rights with respect to products made from the protected process. Under today's laws, U.S. process patent holders have two ways to protect themselves against imports made with the process without the patent owners' permission. These Americans can bring a case before the International Trade Commission under Section 337 of the 1930 Trade Act, or they can apply for patents abroad and seek

to enforce them in foreign courts. Both remedies have a variety of shortcomings, which is why the Administration supports enactment of S.1543.

Let me focus on the problems associated with bringing an action under Section 337, because that is the procedure with which my Agency has the greatest experience. Under Section 337 the patent holder must establish that the product was made with the patented process. This is often impossible since information about practices and production techniques are very difficult to obtain. This kind of discovery procedure is also very costly for the patent holder, thereby all but the largest companies are often precluded from using Section 337. In addition, the patent holder must be prepared to establish that importation will damage an economically and efficiently operating domestic industry. This too is often difficult and costly. The patent holder must also establish that he is injured by the import. Finally, even if the ITC finds in favor of the patent holder, if the goods are already in U.S. commerce, he can get no relief since the ITC cannot award damages: the ITC's remedies are restricting future imports, or issuing a cease and desist order.

The other option available to Americans is equally ineffective. For instance, the patent-holder could try to obtain and enforce patents in a number of foreign countries. But this is both expensive, and often it will prove an empty victory since so many foreign countries do not effectively enforce their laws, or do not allow patenting of processes.

S. 1543 would provide effective protection to Americans against diminishment of their rights due to imports of products made through the unauthorized use of their patents. The Administration

supports S.1543 because it would bring American practice into conformity with that of the other principal industrial nations. Our General Counsel's office has examined S. 1543, and the proposed amendments, and their conclusion is that the bill's provisions are consistent with our obligations under the General Agreement on Tariffs and Trade.

This bill would provide U.S. process patent holders an additional avenue for protecting their rights, which could prove faster and more effective than under existing laws. But we believe the bill will be less effective unless it includes a provision shifting to the importer the burden of proving that the patented process was not used in making the challenged import. The Administration believes that this would not place an unreasonable burden on the importer since he is in a better position to establish whether or not the process was used, than the U.S. process patent holder. In addition such a provision would reduce the costs of discovery proceedings, thereby reducing the costs of protecting the rights granted by patents, making it possible for more companies to prevent foreign misappropriation of their rights.

In order to protect against abuse, the Administration supports requiring the American patent holder to establish certain facts and circumstances suggesting that his process was used, before the burden would shift to the importer. The elements which the plaintiff would have to establish are outlined in the Department of Justice testimony.

In addition, the Administration supports amending S. 1543 so it applies only to products directly produced by the patented process. We recognize that there is a danger associated with

this change: that some products may enter the United States which contain an important component made with the patented process, while the final product was not. We are prepared to work with your Committee to find an appropriate solution.

Mr. Chairman, the Administration supports the central thrust of S. 1543. We believe the bill would promote innovation in some of our most dynamic sectors, such as: pharmaceuticals; solid state electronics; new types of metals; and and industries making use of developments in biotechnology. Its adoption would bring U.S. laws into conformity with those of the other industrial nations. But most importantly, it would improve the protection available to Americans against the actions of foreigners which severely diminish the value of their process patents. The Trade Policy Review Group and the Economic Policy Council have reviewed the process patent issue, and, essentially, this is a bill which the Administration can support.

OFFICE OF THE UNITED STATES
TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON
20506

January 29, 1986

Honorable Charles McC. Mathias, Jr.
Chairman, Subcommittee on Patents,
Copyrights and Trademarks
Senate Judiciary Committee
Washington, D. C. 20510

Dear Mr. Chairman:

Commissioner Quigg has provided detailed answers to your supplemental question on our testimony on S. 1543. I have had a chance to review those answers and I concur with them.

Sincerely,

Harvey Bale
Assistant U.S. Trade Representative
for Trade Policy and Analysis

Senator MATHIAS. Thank you very much.

Let me just put several questions to you at large, and you can jump in and respond as you see fit. What is the international outlook on this kind of proposition? It has been said that all of our major trading partners give domestic process patents the kind of protection that is proposed in Senate bill 1543. Let us be specific about some of them. What about Great Britain? What about Germany? What about Japan? So that we know what the actual practice in these countries is.

Are there any differences in the other patent systems—differences such as the working requirements or compulsory licensing provisions in some foreign patent statutes—that would make their treatment of process patents different from what is being proposed in Senate bill 1543, and different in ways that makes the comparison difficult or questionable?

Mr. Bale.

Mr. BALE. I think I will defer to Mr. Quigg, whose staff, I think, has been doing some very good work in this area, and we have seen, in fact, a table which they have prepared on that matter.

Senator MATHIAS. All right. Commissioner?

Mr. QUIGG. Attached to my written statement is a table which does indicate the countries which provide for protection via process patent of the process direct products. And practically all of the developed countries do have such a provision.

You asked whether or not the working requirements pose a different problem. Working requirements in foreign laws do not pertain to just importation. All those working requirements pertain to is whether or not you worked your patent within a given period of time, generally 3 years; if you have not done that, then you are subject to having a compulsory license granted to another party. But the importation protection still exists, just as it would in this bill that we are supporting today.

Senator MATHIAS. Are there any other comments on that question?

Mr. BALE. I am just wondering, when it comes to the question of—and it is more of a question, perhaps, for discussion—when it comes to the problems that many chemical producers and other patent holders face overseas on the compulsory licensing issued you wonder if in fact that fact does not lend itself perhaps all the more to legislation such as this, to the extent to which foreign countries acquire the ability to produce certain products which may hold process patents here. Just a bit of a thought on the point that you made, Senator, that in fact, compulsory licensing does exist abroad, it does not. With regard to the existence of that compulsory licensing and the perhaps reimportation problem that might exist, I wonder if that, in fact, does not add to the utility of this legislation to the extent that such products produced abroad with U.S. process patents which in turn under those laws may be legal, but then which may infringe on U.S. process patents. It is more of an issue which I've thought of in the context of your question.

Senator MATHIAS. I do not want to ask a question which will be clear from some study of the material you have submitted, Commissioner, but it does seem to me interesting where these other countries place the seller or user of the imported product. Do they

hold only the foreign manufacturer liable, the foreign manufacturer who exports into a given country, or do they also hold liable the seller or the user of the imported product?

Mr. QUIGG. They would hold the foreign manfacturer liable if they could get jurisdiction. That generally is the problem. So in the absence of——

Senator MATHIAS. He ought to be the target of first resort.

Mr. QUIGG. Yes; but in most instances, he is not available in that jurisdiction, and the only way that you can get the protection for the patent owner is to make the user and the seller liable. And of course, that is exactly what our patent law says, and the others do, too, that you get the right to exclude others from manufacturing, using and selling. So even if the manufacturer is outside the country, you still have those two elements, use and sale, that the patent owner should be able to control.

Senator MATHIAS. How does this operate? Does it make any distinction between the domestic infringers and the subsequent sellers and users of an imported product?

Mr. QUIGG. As it stands right now, I do not believe the bill makes a distinction.

Senator MATHIAS. If you are an infringer, it does not matter to the process patent holder?

Mr. QUIGG. Right.

Senator MATHIAS. My question really went to other countries. Do other countries make a distinction between the domestic infringer and an infringer by way of importing?

Mr. QUIGG. To the best of my knowledge, they do not.

Senator MATHIAS. Do you agree with that, Mr. Bale?

Mr. BALE. As far as we know.

Senator MATHIAS. Now, there are a number of proposals that have been made to strengthen the international protection of the U.S. intellectual property, through trade remedies rather than through legal remedies, through the judicial process.

Now, this bill moves in the opposite direction because it does create a legal remedy, which is justiciable for what is currently being handled by the International Trade Commission under the Trade Act.

I anticipate that some of the testimony today will suggest that if the remedy in S. 1543 is enacted that we ought to repeal the existing remedy in the Trade Act.

What would be the administration's reaction to that kind of suggestion?

Mr. BALE. We would not support that position, Senator. The 337 statute, 337(a), would still serve a utility to a patent holder. Certainly, repeal across the board would not be warranted. In fact, the administration has suggested again as part of its trade legislative package—that is, items it feels it can support in the Congress—certain modifications to 337; but certainly not repeal, because of the utility and perhaps the speed and the time limitations on 337 that continue to make 337 a viable option for producers and domestic holders of patents to achieve relief in the event of valid infringement.

So the question of 337 was considered, but never in the context of repeal—even taking into account this proposal on process patents.

Senator MATHIAS. Again anticipating some of the testimony that is likely to be offered later in the morning, there will probably be suggestions for revisions in the grandfather clause in section 3. Would that appeal to you, Commissioner?

Mr. QUIGG. I think to a certain extent it appeals to me. The second sentence of section 3 of the bill, it seems to me, is too broad. I think that it probably should be narrowed to simply extend to those products that have previously been contracted for, rather than some concept that maybe production will take place in the future. That opens an awfully big door that probably is not justified here.

Mr. Chairman, if I might make a comment on 337 also, I think that it is important to keep 337, because this is a short-term compact operation which the patent owner can use to prevent the market from slipping away to foreign manufacturers. Patent litigation in the Federal courts is a more prolonged thing. It is not likely that you would be able to get a preliminary injunction during the litigation, and therefore the 337 approach does have a benefit for U.S. patent holders.

Senator MATHIAS. Before I yield to Senator Leahy, let me just address one further question. Isn't it likely that one consequence of the enactment of 1543, even without any question of presumption, would be that importers of products will feel obliged to ask the question, they will be under some notice that they will be charged with some knowledge of the fact about whether or not the products they are importing are made using the patented process. So, if that is the case, wouldn't normal discovery procedures lessen the obstacles to the proof of infringement sufficiently to make presumptions unnecessary?

Mr. Ginsburg, do you want to tackle that one?

Mr. GINSBURG. Senator, I think that it is reasonable to expect that the more conscientious and legitimate importers would indeed concern themselves to a greater degree with the question of whether the goods they are importing infringe a U.S. patent, if any legislation of this sort is enacted, because they could find themselves otherwise enmeshed in litigation that may be more expensive than the importation is worth to them.

I think we would have to be concerned, however, also with the phenomenon of firms importing either knowingly or where they have certainly good reason to think that their products are indeed infringing, not putting themselves in the position to determine that, even though they really have the superior opportunity to do so. Our patentee who does bring suit will, as the Commissioner described, typically be unable to obtain jurisdiction over the foreign manufacturer, and yet the importer will have been in privity of contract with that manufacturer and could, if legally obliged to do so, quite readily be expected to determine the character of the goods.

So while I think that any legislation would heighten protection for valid patents, we are concerned that we not take only a half measure here where a full measure is required.

Senator MATHIAS. Thank you.

Senator Leahy.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Senator LEAHY. Thank you, Mr. Chairman.

First, Mr. Chairman, might I say that I appreciate the fact that you are having these hearings. I think that there is a great need for legislation in this area. There is really no justification for allowing the importation of products manufactured overseas by processes patented here in the United States, without there being some kind of protection or compensation.

I am concerned, however, that some aspects of the legislation may go farther than I would prefer. I wonder if you could help me with a little bit of history. You people are far more expert in this area than any of us. You deal with it every day. This may not come as a big shock to any of you, but there are occasions during the day when both Senator Mathias and I concern ourselves with issues other than patent law—we feel guilty when that happens, of course, and immediately get back into this arena. But can you tell me why process patents were treated differently in the law from product patents in the first place? Would anybody like to take a stab at that—why process patents have been treated differently from product patents since the beginning.

Mr. QUIGG. I do not know why they made that distinction. Of course, our law was much earlier than most of these others in developed countries, and as those laws came along, I think they saw the need for this protection because of the small areas and the adjacent potential for importation.

We had a couple of oceans out there that were sort of protecting our shores back in the early days, and that has disappeared with present transportation.

Senator LEAHY. It is a little bit different taking a Pan Am clipper than taking a clipper ship—is that what you are saying?

Mr. QUIGG. I think we could say that, yes.

Senator LEAHY. Is that why the users and sellers of products of processes patented in the United States were not subject to liability for infringement when those products were manufactured in the United States?

Mr. QUIGG. Well, in the United States, of course, a process patent holder can get jurisdiction over the manufacturer. That is the real distinction between the foreign importation and the manufacture in this country. So it was not nearly as important that you have process patents covering the direct product in the United States because you could go to that initial source of the infringement.

Senator LEAHY. Last night, I stopped in a drugstore out near where we live to pick up some batteries. And I could not help but wonder, just looking at all the things in there—I am thinking now mostly of the patented medicines that line the shelves—whether it really is realistic to require that a retailer, whoever the retailer might be at that particular drugstore, know by what processes all those products are made by? I mean they probably have tens of thousands of products in there.

Under the proposed law, it seems like they have got to have all that somewhere in the back of their minds, don't they?

Mr. GINSBURG. Senator, if I may address that, it is currently the state of the law that the retail pharmacist, for instance, could be held accountable for an infringement insofar as he sells infringing goods manufactured wherever.

As a practical matter, however, plaintiffs do not concern themselves with suits against retailers where their concern is with the source of the goods. They would have to sue every retailer separately if they were to take that approach, and it is more efficient for them, of course, to go as far up the chain of distribution——

Senator LEAHY. Well, would they have to sue everyone separately? I mean, some of these drugstores are pretty big and have a lot of insurance and a large capital flow, like some of these big shopping center stores. They still may not be national. It may be a local large chain store. If somebody wanted to go after the store for damages, would it not make sense on the theory that the store does not have the resources to fight such a suit. The store might well want to settle or tell the insurance company, "Come on, get them off my back and pay it," don't you think?

Mr. GINSBURG. Senator, I do think that the experience in this field is to the contrary, and that while there may be instances of that sort, the patentee is normally most interested in reaching as far back to the root of the problem as possible in order to stop it.

Of course, large distributors, large retailers of the sort to which you are referring, I think, do take precautions to determine that the goods that they purchase for resale are lawful in every respect, that they conform to safety laws and so on, as well as that there are not patent infringements or that they receive indemnification from the manufacturers in the event that it is held to the contrary.

Senator LEAHY. And of course, that indemnification is good only to the extent that the manufacturer backs it up, is it not? I mean, if a suit is brought against the retailer and the retailer loses, he can then seek indemnification from the manufacturer if the manufacturer is still there and solvent.

Mr. GINSBURG. If there is a doubt about that, I would think that that could constitute a disincentive for a large retailer to purchase from that manufacturer, as it is clearly a disincentive to purchase inherently dangerous products from a manufacturer that cannot back them up and make good on the liability claims.

Senator LEAHY. So would I be safe in thinking that you do not feel this bill goes too far?

Mr. GINSBURG. That is correct, Senator. I think it is important to bear in mind that we are dealing with a gap in an already existing regime under which, for instance, the sale constitutes an infringement, with the sole exception where the infringement is of a—oh, pardon me—that is the law without exception. It is simply not very useful where the infringement is of a process patent that was violated abroad.

Senator LEAHY. And so you feel that the reason process patents were treated differently than product patents in the first place is really a historical anomaly, reflecting commercial practices at that time, and not based on some kind of a jurisprudential background?

Mr. GINSBURG. Senator, I did ask my staff that question——

Senator LEAHY. Excuse me. Does that correctly summarize what you said, sir?

Mr. QUIGG. Yes, that is my position. I think I might also point out that from a realistic standpoint, no patent owner likes to sue his potential market. He would rather go against the manufacturer, who is a competitor.

Senator LEAHY. You anticipated my next question. Thank you.

Yes, sir, you were going to say something?

Mr. BALE. I have nothing to say, sir.

Senator LEAHY. Well, I do not mean to cut you off. I just wanted to be sure—he had nodded "Yes," and unfortunately, the reporter cannot show a nod. That is the only reason I wanted to get that on the record. OK.

Mr. Chairman, thank you very much.

Senator MATHIAS. Thank you, Senator Leahy.

Gentlemen, you have said that you thought this legislation had more importance than merely providing redress for individual manufacturers whose process patents are violated. I think, Mr. Bale, you said you felt this had an impact on the overall trade picture of the United States.

Now, Senator Lautenberg in his statement made a similar statement. He said:

> In 1982, the International Trade Commission estimated that infringement of the United States intellectual property cost the Nation's businesses $5.5 billion in annual sales and cost Americans 131,000 jobs in five industries.

Now, of course, he refers generally to U.S. intellectual property infringements. That could go beyond process patents. But those are substantial figures. I am wondering if you have any more precise estimates of where this particular aspect of process patent infringement falls?

Mr. BALE. Well, Senator, I do not think we have—at least, I do not have available to me now—more precise figures in terms of absolute dollars. But when one looks at some of the figures—and I only cited the case of Korea in my written testimony—information which was supplied to us by the Pharmaceutical Manufacturers Association. According to their figures, if one looks at Korea and legitimate sales in Korea of pharmaceutical products of U.S. brands or U.S. products, U.S. companies' products, and unauthorized sales, the ratio is on the order of 3 to 1 in favor of the unauthorized sales.

And Korea is not alone. In Taiwan and many other countries, Brazil and Mexico, where there is a substantial amount of sales and production of products for which Americans hold valid patents, the risk is very high of products being traded internationally, including in this market. This is the most lucrative market in the world. And this is why many, many Japanese, European innovators take out patents here, and that is fair, but this is also why one has to suspect that the volume of trade that may involve infringements of U.S. process patents could be substantial.

I am not sure one can put a number on that, because of the chilling effect, perhaps, of the impediments. First of all, there is the noninclusion in U.S. patent law of the ability to take this into court, and the obstacles of the 337 process at various points involving injury, industry, economically inefficiently operated, and the discovery problems that my colleagues have alluded to before that

exist in this area, may in fact prevent us from getting firm numbers in an aggregate sense on this problem.

But the fact remains that pirating and unauthorized sales generally of U.S. pharmaceuticals, electronics, is quite widespread internationally, and how that could not impact us substantially, I just cannot imagine.

Mr. GINSBURG. Senator, if I may add to that, I would point out that attempts of this sort to measure the magnitude of the effect that the lack of legal protection for intellectual property rights may have are inherently limited, because the nature of the effect is, in part, to deter investment in innovation and the development of patentable processes and products in the first place. These figures relate to estimates of infringing trade with respect to patents that were brought into being. We do not know how much we are losing by way of foregone innovation because of the failure to protect the fruits of that innovation adequately. And when the great research laboratories of the United States, the Bell Labs and the pharmaceutical houses, make their investment decisions in research, they must certainly do so with an eye to whether it will yield results of the type that will be adequately protectable under our laws.

Senator MATHIAS. But could you say this, that although you cannot quantify it in precise dollars, that the volume is sufficiently great to be of some significance in our overall trade picture, and beyond the question of individual rights that are contemplated here—not that the individual rights are not important; I do not want to imply that, but I just want to see what your feeling is about the overall impact.

Mr. GINSBURG. We think the figures that the ITC developed and that Mr. Bale referred to suggest that we are talking about a phenomenon with an already noticeable impact on our trade position, the redress of which should help our trade position in a meaningful way, but that the unmeasurable aspect of this may, indeed, be in the long run of the greatest significance to our trade position.

The creation of knowledge is the basis for our ability later to produce and export products that embody that knowledge.

Senator MATHIAS. And that, of course, is increasingly true as we move through this transitional period in which we become a center of service industries for the future.

Mr. GINSBURG. Senator, we are becoming a center of service industries and a center of learning and research. We bring thousands of students from abroad every year to study at our universities, and we generate more new technology, almost certainly, than any other country, and perhaps than all of the other countries with which we compete. But we are losing that edge and will continue to do so, in my judgment, if we do not adequately protect the fruits of that effort.

Senator MATHIAS. Gentlemen, I thank you for being here.

It is unfortunate that, as is usually the case in the Senate, there is competition for this hearing this morning. Secretary Baker is in Foreign Relations, and there are other hearings going forward in which members of this committee would like to be present, but are obliged to be other places.

So if it is agreeable to you, I would like to keep the record open so that members who have questions can submit them to you in writing to be included in the record. And there may be questions that will occur to me in the light of subsequent testimony that we may also wish to propose to you.

So if that is agreeable, we will leave the record in that state, and your responses will be included as part of your testimony.

Thank you very much.

Our next panel includes: Hon. Donald W. Banner, president of the Intellectual Property Owners; Hon. Gerald Mossinghoff, president of the Pharmaceutical Manufacturers Association; Roy H. Massengill, general patent counsel of Allied-Signal; Dr. Marc Ostro, president of the Liposome Co.; and Mr. Nolan Hancock, of the Oil, Chemical & Atomic Workers International Union.

Gentlemen, during the last panel's testimony, you may have noticed that we installed the "traffic lights." This is no invidious discrimination against this panel as against the last one; we simply did not have the equipment in the room. But we do have some rather severe time limits this morning. Would it be too harsh to limit you to a 3-minute oral statement, and your written statements be included in the record?

If there is no objection to that, we will start with Mr. Banner.

STATEMENT OF A PANEL, CONSISTING OF DONALD W. BANNER, PRESIDENT, INTELLECTUAL PROPERTY OWNERS, INC., WASHINGTON, DC; GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, DC; DR. MARC J. OSTRO, VICE CHAIRMAN AND CHIEF SERVICE OFFICER, THE LIPOSOME CO., PRINCETON, NJ; ROY H. MASSENGILL, ESQ., GENERAL PATENT COUNSEL, ALLIED-SIGNAL, MORRISTOWN, NJ, AND NOLAN HANCOCK, ESQ., ON BEHALF OF OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION, WASHINGTON, DC

Mr. BANNER. Thank you, Senator.

Mr. Chairman, I am here in behalf of Intellectual Property Owners, and we appreciate the opportunity to present our views here this morning, very briefly.

I might say at the outset that I do not think I will need my 3 minutes, because most of the things that need saying have been said.

I would add, however, that we do strongly support this legislation.

Senator MATHIAS. You have been here before, so your record is already well known.

Mr. BANNER. Yes, sir. You made reference this morning to the fact that we are talking about closing a loophole, and I will say that is exactly what we are doing. We are closing a loophole in our law which has already been closed by our trading partners. This loophole obviously has an impact on jobs in America, and obviously has an impact on our trade deficit.

One wonders why it has taken us so long to close this loophole. We have been talking about legislation like this, to my knowledge,

since at least 1966, and I suggest that Congress must come now to take action on these matters.

I invite your attention to the fact that appended to the Intellectual Property Owners' statement are the names of 73 U.S. companies, and 12 national associations which favor legislation along the lines of this bill. We have recommended some modifications. Some of the people who are on this list favor certain modifications, but in general they are certainly all very supportive of the legislation and heartily recommend it. And we congratulate you for your role in introducing it, and we hope that it will have a speedy passage.

Thank you, Mr. Chairman.

Senator MATHIAS. Thank you very much, Mr. Banner.

[Mr. Banner's submissions for the record follow:]

PREPARED STATEMENT OF DONALD W. BANNER

SUMMARY

IPO STRONGLY SUPPORTS S. 1543. IT WILL HELP STOP THE LOSS OF MANUFACTURING JOBS FROM THE UNITED STATES.

- The decline in U.S. competitiveness is attributable in part to weaknesses in the patent system which have weakened the incentives for R&D.
- Stronger U.S. patent rights will benefit U.S. companies most because U.S. companies still own some 70 percent of U.S. patents currently in force and U.S. companies are closest to the U.S. market.
- S. 1543 will help preserve jobs in the United States by prohibiting competitors of the patent owner from manufacturing offshore using the patented process. The patent owner is more likely to manufacture in the U.S. if protected in the U.S. from offshore free riders.
- Our major trading partners, including Japan, West Germany, France, and the United Kingdom, have provisions in their laws similar to S. 1543. We should provide at least as much protection for manufacturing processes as other countries provide.
- The only remedy currently available to U.S. process patent owners -- an exclusion order from the U.S. International Trade Commission under section 337 of the Tariff Act -- is inadequate.
- S. 1543 is entirely consistent with the aims of the Drug Price Competition and Patent Term Restoration Act of 1984.
- S. 1543 contains a safeguard to protect innocent infringers, including retailers. Moreover, retailers almost always are protected by hold-harmless clauses and the Uniform Commercial Code.
- IPO suggests a few refinements in the language of the bill.

* * *

Mr. Chairman and members of the Subcommittee:

Thank you for this opportunity to discuss S. 1543, the "Process Patent Amendment of 1985." We strongly support S. 1543. It should be enacted without delay to help stop the loss of manufacturing jobs from the United States.

IPO is a nonprofit association whose members own patents, trademarks, and copyrights. Our members include

large corporations, small businesses, universities, and individuals.

IPO members are responsible for a large portion of the research conducted in the United States. We believe an effective patent system is very important in encouraging research and commercial development of new technology.

The United States can no longer afford to neglect matters which affect the climate for invention and innovation. The evidence is overwhelming that our industrial competitiveness is slipping.

In 1984, seven of the eleven corporations which received the largest numbers of U.S. patents were foreign-controlled. Ten years ago, only three of the top eleven were foreign-controlled.

In the late 1960's the percentage of U.S. patents going to foreign nationals was about 20 percent. Last year it was 41.7 percent. The share going to Japanese nationals alone has risen to 16 percent.

Statistics such as these probably were interesting only to patent lawyers at one time. Today, more and more people are beginning to realize that such trends have a correlation with the number of jobs in our country.

IPO believes the declining share of patents going to our own citizens can be attributed in part to weaknesses in the patent system which, in turn, have weakened the incentives for our citizens to make inventions. We must provide greater incentives for American firms to invest in research, development and commercialization of technology.

Several studies, going back at least as far as the President's Commission Report of 1966, have recommended improvements in the functioning of the patent system. The 17-year exclusive patent right to manufacture, use, and sell inventions can give powerful incentives when the patent laws and procedures operate effectively.

A strong U.S. patent system is of greatest benefit to American companies because American companies still own a substantial majority of the patents issued in the United States -- about 70 percent of patents currently in force -- and because American companies are the ones with the best understanding of, and closest proximity to, U.S. markets.

U.S. patent law does not require patent owners to manufacture in this country. Neither do our trading partners, for the most part, require manufacturing in their countries when they grant patents to U.S. companies. U.S. patent law does, however, block competitors from manufacturing offshore and importing into the U.S., if the patent is a product patent. When U.S. patent owners are protected from offshore competition they are more likely to manufacture in the U.S. themselves, creating jobs in this country.

S. 1543 would eliminate a longstanding loophole in U.S. patent law which encourages manufacturing abroad using processes developed and patented in the United States. Under existing U.S. patent law, infringement of a patent occurs when someone (1) makes, uses, or sells a product in the United States covered by a product patent or (2) practices a process in the United States covered by a process patent. It is not an infringement of a U.S. process patent if a competitor uses a patented process outside the United States to manufacture a product and then imports that product into the United States.

S. 1543 broadens the definition of patent infringement to cover the acts of importing into the United States or using or selling in the United States a product produced in another country by a process patented in this country. This change would prevent competitors from avoiding a patent merely by moving offshore to do their manufacturing.

Offshore production using patented processes has long

been in need of a remedy. Such a remedy was recommended by the 1966 President's Commission on the Patent System and, more recently, by the 1985 report of the President's Commission on Industrial Competitiveness.

Our major trading partners, including Japan, West Germany, France, and the United Kingdom, have provisions in their laws similar to S. 1543. The European Patent Convention, which has eleven member countries, reads as follows on this point:

> If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

If our country is serious about preserving manufacturing jobs, certainly it should provide at least as much protection for manufacturing processes as other countries provide. If the owners of manufacturing processes covered by U.S. patents can be protected from free riders with no R&D expenses who manufacture offshore, many thousands of jobs can be protected in the United States.

Patented processes can be highly valuable. Allied-Signal Incorporated's patented amorphous metal alloys process technology, the subject of a recent U.S. International Trade Commission case, was found by the ITC to have a U.S. market value in excess of a billion dollars a year. A patent owned by Corning Glass Works covering a patented manufacturing process for optical fiber waveguides, also the subject of an ITC case, is a basic patent in a multi-billion dollar telecommunications industry.

Process patent legislation is especially important to the emerging biotechnology industry in America. In the biotechnology field, often the only protection available is a process patent.

Although owners of U.S. process patents sometimes can obtain relief from the ITC in the form of an exclusion order

under section 337 of the Tariff Act, that remedy is inadequate for several reasons:

1. The patent owner cannot obtain damages from the ITC, but only exclusion orders preventing importation;

2. ITC proceedings are more expensive and uncertain for patent owners than patent infringement litigation in federal district courts, because of the need in ITC proceedings to prove injury to an efficiently and economically operated domestic industry;

3. Temporary relief is almost impossible to obtain from the ITC;

4. Attorney fees are unavailable from the ITC; and

5. Relief can be denied by the ITC or overruled by the President for "policy" reasons.

We are aware that S. 1647 has been introduced in the Senate recently to strengthen the relief available under section 337 of the Tariff Act for patent, trademark, and copyright owners. We are in favor of that kind of legislation, but it should not be regarded as a substitute for S. 1543. Even if all of the provisions of S. 1647 are enacted, section 337 relief -- by its nature -- will not be a complete remedy for patent owners. For example, monetary damages would still be available only in patent infringement suits in the federal district courts.

S. 1543 is entirely consistent with the aims of the Drug Price Competition and Patent Term Restoration Act of 1984, which allows quicker marketing of generic drugs after patents expire, but also strengthens incentives provided by patents for companies and inventors to perform research and development. S. 1543 would strengthen incentives for R&D on manufacturing processes in the drug industry, and in all other industries, by preventing competitors from taking a free ride on the results of the patent owner's R&D expenditures until the patent expires.

Like existing patent law covering product patents, S. 1543 requires sellers and users to respect patent rights. Retailers, like everyone else, are legally responsible if they infringe patents or sell counterfeit merchandise. By and large, the retailers in this country have respected the rights of inventors and patent owners. Further, retailers almost always are protected by hold-harmless clauses, as well as by section 2-312(3) of the Uniform Commercial Code. The UCC provides that a seller normally warrants against claims of patent and trademark infringement by third parties, unless the seller and buyer agree otherwise.

Retailers are no more likely to be sued for infringement of process patents under S. 1543 than they are to be sued for product patent infringement today. Retailers usually are not in a position to judge for themselves whether a patent is being infringed. They must rely on their suppliers and manufacturers to make these judgments. S. 1543 provides specifically in section 2(c) that retailers and other purchasers are not liable unless they know of, or are notified of, infringement.

Once purchasers were notified of infringement of a process patent, S. 1543 would make them proceed at their peril. This is as it should be. Purchasers proceed at their peril today after they are notified of product patent infringement. There is no other way to insure respect for patent rights.

Although the purpose of S. 1543 is to protect patent owners from importation of goods made overseas by using a process patented in the United States, the wording of the bill is broad enough to make sellers and users of products made in this country by a patented process liable for infringement as well. As we understand it, the bill was drafted this way to allay fears expressed by some authorities that the bill otherwise might violate our

country's obligation under the General Agreement on Tariffs and Trade (GATT) not to discriminate against foreign-made products.

We believe this issue is not of much practical consequence, because a patent owner invariably would elect to file suit against the manufacturer if the manufacturing was occurring in the United States. Nevertheless, we suggest that the Subcommittee should study whether the GATT in fact requires the bill to cover products manufactured in this country by a patented process. If the GATT does not require coverage of products manufactured in this country, the bill could be limited to products manufactured abroad, because the remedy provided by the bill is needed only to protect against imports.

Another point on which the Subcommittee should consider refining the bill concerns the circumstances in which a presumption of infringement should arise when the patent owner is unable to obtain information about the process used to manufacture a product. It can be very difficult to obtain information about the process used to manufacture a product if jurisdiction cannot be obtained over the foreign manufacturer.

The U.S. International Trade Commission has recognized a presumption of infringement in certain situations under the Tariff Act. A similar presumption is essential in cases under the patent code if S. 1543 is to be effective.

The text of S. 1543 is silent on when such a presumption should arise. Some earlier bills have included a provision to the effect that the product shall be presumed to have been made by a patented process if the patent owner has tried without success to determine the process actually used and the court finds a substantial likelihood that the product was produced by the patented process.

We recognize that the sponsors of the legislation plan

to make clear in the committee report that the committee intends for courts to apply a presumption in appropriate cases, but we believe the best way to ensure the intended result is to include a definition of the presumption in the bill itself.

Section 3 of S. 1543 is a "grandfather" clause which exempts certain existing supply arrangements from the coverage of the bill. We believe the exemption granted by this section is broader than necessary. The first sentence of the section correctly limits the effect of the bill to products produced or imported after the date of enactment. The second sentence, however, which exempts products "already in substantial and continuous commercial production", should be eliminated or at least narrowed.

Maximum incentives for patent owners to manufacture in the United States would be achieved by deleting the second sentence entirely. We see no compelling reason to allow foreign manufacturers who are currently taking a free ride on the R&D investments of U.S. process patent owners to be allowed to continue to do so. If the second sentence is retained, the phrase "commercial production" should be changed to "sale or use in the United States", and the reference later in the same sentence "to investments made or business commenced" should be limited to the United States.

* * *

We urge the subcommittee to approve S. 1543 at an early date. This kind of legislation has widespread support from innovative U.S. firms. The appendix to our statement lists 73 companies and 12 associations which have authorized us to state that they favor enactment of legislation on process patents.

We appreciate the opportunity to present our views.

"APPENDIX"

October 17, 1985

SUPPORTERS OF PROCESS PATENT LEGISLATION

We, the organizations listed below, support legislation giving the owner of a process patented in the U.S. the right to bring a suit for patent infringement against a party who imports a product which is manufactured abroad by using the process.

This legislation will keep foreign manufacturers from taking a free ride on R&D expenditures of U.S. companies. It will preserve jobs of U.S. workers. The proposed legislation is similar to provisions already in the patent laws of most industrialized countries.

We urge Congress to enact this legislation at an early date. If we can be of any assistance, please do not hesitate to call on us.

COMPANIES

AMERICAN CYANAMID CO.
Wayne, NJ

AGRIGENETICS CORP.
Boulder, CO

AIR PRODUCTS AND CHEMICALS, INC.
Allentown, PA

ALLIED-SIGNAL INCORPORATED
Morristown,

ALUMINUM COMPANY OF AMERICA
Alcoa Center, PA

AMERICAN HOME PRODUCTS CORPORATION
New York, NY

AMGEN
Newbury Park, CA

AMOCO CORPORATION
Chicago, IL

ARMSTRONG WORLD INDUSTRIES, INC.
Lancaster, PA

ASHLAND PETROLEUM CO.
Ashland, KY

BATTELLE MEMORIAL INSTITUTE
Columbus, OH

BAXTER TRAVENOL LABROATORIES, INC.
Deerfield, IL

BECTON, DICKINSON AND COMPANY
Paramus, NJ

CORNING GLASS WORKS
Corning, NY

CPC INTERNATIONAL, INC.
Englewood Cliffs, NJ

BIOTECHNICA INTERNATIONAL, INC.
Cambridge, MA

THE BLACK & DECKER CORP.
Towson, MD

THE BOC GROUP, INC.
Montvale, NJ

BMC INDUSTRIES, INC.
Saint Paul, MN

BORG-WARNER CORPORATION
Chicago, IL

BRUNSWICK CORP.
Skokie, IL

CALGENE, INC.
Donis, CA

CALIFORNIA BIOTECHNOLOGY INC.
Mountainview, CA

CATERPILLAR TRACTOR CO.
Peoria, IL

CETUS CORPORATION
Emeryville, CA

CHEVRON RESEARCH COMPANY
San Francisco, CA

CIBA-GEIGY CORPORATION
Ardsley, NY

COMBUSTION ENGINEERING
Stamford, CT

JOY MANUFACTURING COMPANY
Pittsburgh, PA

THE LUBRIZOL CORP.
Wickliffe, OH

DAMON BIOTECH
Needham Hts., MA

DIAMOND SHAMROCK CHEMICALS CO.
Painesville, OH

DOW CHEMICAL CO.
Midland, MI

DOW CORNING CORPORATION
Midland, MI

DRESSER INDUSTRIES, INC.
Dallas, TX

DuPONT COMPANY
Wilmington, DE

ELI LILLY AND COMPANY
Indianapolis, IN

ENERGY CONVERSION DEVICES, INC.
Troy, MI

ENGLEHARD CORPORATION
Iselin, NJ

FMC CORPORATION
Philadelphia, PA

GENECOR, INC.
San Francisco, CA

GENERAL ELECTRIC COMPANY
Fairfield, CT

GENEX CORP.
Rockville, MD

GERBER SCIENTIFIC, INC.
South Widsor, CT

HOFFMANN-LA ROCHE
Nutley, NJ

ILLINOIS TOOL WORKS INC.
Chicago, IL

STAUFFER CHEMICAL COMPANY
Westport, CT

SUN REFINING AND MARKETING COMPANY
Philadelphia, PA

TECHNION, INC.
Irvine, CA

TEXACO DEVELOPMENT CORPORATION
White Plains, NY

3M
Saint Paul, MN

TRW
Cleveland, OH

MANVILLE CORPORATION
Dayton, OH

MERCK & COMPANY, INC.
Rahway, NJ

MILLIKEN RESEARCH CORPORATION
Spartanburg, SC

MONSANTO CO.
Saint Louis, MO

MORTON THIOKOL, INC.
Chicago, IL

MYCOGEN
San Diego, CA

PFIZER, INC.
New York, NY

PHILLIPS PETROLEUM COMPANY
Bartlesville, OK

POLAROID CORPORATION
Cambridge, MA

THE PROCTER & GAMBLE CO.
Cincinnati, OH

ROHM AND HAAS COMPANY
Philadelphia, PA

SCHERING-PLOUGH CORP.
Madison, WI

SHELL OIL COMPANY
Houston, TX

THE SINGER COMPANY
Fairfield, CT

SMITHKLINE BECKMAN CORP.
Philadelphia, PA

STANDARD OIL COMPANY OF OHIO
Cleveland, OH

UNION CARBIDE CORPORATION
Danbury, CT

UNITED TECHNOLOGIES CORPORATION
Hartford, CT

THE UPJOHN COMPANY
Kalamazoo, MI

VARIAN ASSOCIATES, INC.
Palo Alto, CA

WESTINGHOUSE ELECTRIC CORPORATION
Pittsburgh, PA

55-522 O - 86 - 3

ASSOCIATIONS

AMERICAN TEXTILE MANUFACTURERS INSTITUTE, INC.
Washington, DC

CHEMICAL MANUFACTURERS ASSOCIATION
Washington, DC

ELECTRONIC INDUSTRIES ASSOCIATION
Washington, DC

INDUSTRIAL BIOTECHNOLOGY ASSOCIATION
Rockville, MD

INTELLECTUAL PROPERTY OWNERS, INC.
Washington, DC

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
Washington, DC

NATIONAL ASSOCIATION OF MANUFACTURERS
Washington, DC

NATIONAL SMALL BUSINESS ASSOCIATION
Washington, DC

PHARMACEUTICAL MANUFACTURERS ASSOCIATION
Washington, DC

SMALL BUSINESS LEGISLATIVE COUNCIL
Washington, DC

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION
New York, NY

U.S. CHAMBER OF COMMERCE
Washington, DC

* * *

(Names of contact people in the organizations listed above may be obtained by calling (202)466-2396. Additional organizations will be added to the list shortly.)

REPLIES BY INTELLECTUAL PROPERTY OWNERS, INC.

TO QUESTIONS DATED NOVEMBER 15, 1985 FROM SENATOR MATHIAS

QUESTION 1. Why is it necessary to hold the purchaser of the foreign product liable under the bill, if he uses or sells it in this country, rather than just targeting the foreign manufacturer who uses the patented process, then exports the product into this country? Why isn't it possible in all these cases to get jurisdiction over the foreign manufacturer, and so cut this activity off at its source?

REPLY: The foreign manufacturer may have insufficient contacts with the United States to be sued in U.S. courts. The foreign manufacturer may, for example, be selling the products to another party abroad who then imports into or distributes or sells in this country. Users and sellers of products covered by product patents always have been held liable in the United States. S. 1543 in essence extends the same protection to process patent owners which is enjoyed already by product patent owners.

U.S. patents cannot, of course, be enforced outside the borders of this country. Suits in foreign countries to enforce foreign patent rights often are not a satisfactory alternative for a U.S. patent owner. U.S. companies often cannot afford the expense of obtaining patents in all countries where manufacturing might occur. Also, foreign patent laws often do not provide effective enforcement procedures and often do not cover all fields of technology.

Purchasers of products which infringe patents or trademarks have a right to be indemnified by the manufacturer. This was the rule in the United States under the common law. The Supreme Court of the United States confirmed at least as early as 1912 that a purchaser "has a right to assume, in the absence of knowledge, that the seller passes an unconditional title to the machine, with no limitations upon the use." Henry v. A.B. Dick Co., 224 U.S. 1, cited in A. Squillante and J. Fonseca, Williston on Sales, sect. 15-15, at 378 (4th ed. 1974). This rule is embodied in section 2-312 (3) of the Uniform Commercial Code. The UCC provides that a seller normally warrants against claims of patent and trademark infringement by third parties, unless the seller and the buyer agree otherwise. Moreover, retailers often insert "hold harmless" clauses in contracts with suppliers to protect themselves from patent and trademark infringement claims. The potential expense to manufacturers of indemnifying customers helps deter manufacturers from infringing.

QUESTION 2. A process patentee bears the burden of proof in ITC proceedings, and in ordinary patent litigation, even if the defendant is an overseas corporation. Why should the burdens be allocated differently in cases arising under this legislation, if enacted?

REPLY: In ordinary patent litigation, the Federal district court has jurisdiction over the infringing manufacturer and can impose appropriate sanctions if the manufacturer does not comply with discovery requests made by the patent owner. While a patent owner normally bears the burden of proof in ITC proceedings, the ITC may draw inferences against respondents who refuse to disclose information, in effect shifting the burden of proof to the respondent. E.g., In re Certain Multicellular Plastic Film, 2 ITRD 5056 (1979), cited in S.Rep.No. 98-663 at p.6.

QUESTION 3. S. 1543, in contrast to the bill we considered in the 98th Congress, makes it an infringement to use or sell a product made by an infringement of a patented process in the United States as well as overseas. What practical difference does this addition make? How is the power to sue sellers of domestically-produced products likely to be used?

REPLY: The addition makes little practical difference, since patent owners almost always would file suit against the manufacturer if the manufacturing was occurring in the United States. Some authorities expressed fears that the bill considered by the Senate in the 98th Congress might have violated obligations under the General Agreement on Tariffs and Trade (GATT). The bill in the 98th Congress covered products manufactured "in another country". GATT is said to obligate the United States not to discriminate against foreign-made products. On the other hand, the intent of the bill is not to discriminate against foreign products, but only to correct the current situation in which U.S. process patents can be circumvented through offshore manufacturing.

We suggest that your subcommittee should study whether that GATT in fact requires the bill to cover products manufactured in this country. If the GATT does not require such coverage, the bill could be limited to products manufactured abroad.

We believe the power to sue sellers of domestically-produced products would seldom be used. A suit against the domestic manufacturer is the most effective way to cut off infringing activity at the source. Also, patent owners risk alienating potential customers of their own when they sue sellers of competing products.

QUESTION 4. What is likely to be the impact of this legislation on jobs here in the United States? As you know, the generic drug industry has argued that providing this protection would eliminate the incentive that exists under the ITC remedy to maintain manufacturing operations in this country. The ITC remedy requires a showing of injury to an efficiently run domestic industry. But if process patent protection were unavailable under our patent laws, the generic companies argue, it would no longer be a requirement that the patent holder was manufacturing with his process in this country, and so he would probably shift his operations overseas to realize other economic advantages such as cheaper labor. How would you rebut this analysis?

REPLY: We believe strongly that the legislation would help significantly in preserving jobs in the United States. The generic drug industry misses the point when it discusses the impact of the legislation on decisions by the patent owner concerning where to manufacture. The important impact of the legislation would be to stop manufacturing outside the United States by the patent owner's competitors.

By putting a stop to offshore manufacturing by competitors, the legislation would protect jobs created in the United States by the U.S. patent owner. The legislation thereby would encourage manufacturing in the United States by patent owners.

When U.S. patent owners are protected from offshore competition, they are more likely to manufacture in the United States themselves. There are several incentives for a U.S. patent owner to manufacture in the U.S. These include proximity to the large U.S. market and proximity to the patent owner's R&D facilities located in the U.S. Such incentives are less likely to be outweighed by the advantage of cheaper labor abroad if the U.S. patent owner is protected from offshore manufacturing

by competitors who not only may have cheaper labor costs but have no R&D costs.

The ITC remedy gives no incentive for patent owners to manufacture in the United States, because it is an ineffective remedy. In our testimony before the subcommittee, we set forth several reasons for its ineffectiveness. Even if pending legislation to strengthen the ITC remedy is enacted, process patent owners still need enactment of S. 1543 to give them a fully effective remedy against offshore manufacturing by competitors.

QUESTION 5. The Commissioner of Patents testified that S. 1543 should be amended to clarify that it applies only to products directly produced by the patented process. Do you have any comments on this suggestion?

REPLY: This suggestion apparently is supported by technical experts in the U.S. chemical and pharmaceutical industries who understand its effect in the context of a series of chemical reactions. The "directly" limitation is present in at least some foreign laws. We suggest, however, that if this limitation is to be inserted in the bill, the legislative history should explain as clearly as possible what the effect would be on mechanical and electrical technologies, as well as on chemical and pharmaceutical technologies. For example, the legislative history could explain that a product would still be considered produced by a patented process if further, minor modifications were made after the patented process was used.

QUESTION 6. The representative of the National Chain Drug Store Association, suggested that attorney fees should be awarded to the defendant if the plaintiff loses in a case brought under the bill (even if it was brought in good faith). What is your reaction to this suggestion? What, in your view, would a successful defendant have to show under the existing law of attorneys' fees to make out a claim of entitlement to attorneys' fees in a case brought under this legislation, if enacted as introduced?

REPLY: The National Chain Drug Store Association's suggestion is an attempt to solve a problem that does not exist. As explained in the answer to Question 1, retailers are already liable for infringement of product patents, although the Uniform Commercial Code requires their suppliers to indemnify them if they are sued. In practice, manufacturers have almost never sued retailers for product patent infringement. There is no reason to fear manufacturers would sue retailers any more often for process patent infringement if S. 1543 is enacted.

Awarding attorneys' fees against plaintiffs who bring suits in good faith would add to the cost of litigation and would tilt litigation rules unfairly against patent owners. The existing law on attorneys' fees in patent cases, which allows for award of attorneys' fees in "exceptional cases", has worked well. The existing law provides attorneys' fees to either party in the case of bad faith by the other party.

Senator MATHIAS. Mr. Mossinghoff, it is a pleasure to have you back in your translated condition.

STATEMENT OF GERALD G. MOSSINGHOFF

Mr. MOSSINGHOFF. Thank you, Mr. Chairman. I am very pleased to be here.

Mr. Chairman, as a representative of the Pharmaceutical Manufacturers Association, we, too, strongly endorse the enactment of Senate bill S. 1543. We note that that legislation is supported by a broad range of companies and industrial associations, and that the President's Commission on Industrial Competitiveness recommended strengthening process patents.

Mr. Chairman, we note that the principal opposition to the bill comes from a trade association representing manufacturers of generic pharmaceuticals. The PMA represents the 109 pharmaceutical companies who are responsible for the vast majority of new drugs introduced in the United States and virtually all of the pharmaceutical research and development undertaken in this country.

I am also honored to represent the companies in the United States that produce more than 80 percent of the generic drugs that are marketed in the United States. So in that sense, I too represent generic manufacturers. In fact, the majority of the generics sold in the United States are manufactured by our members.

In that light, I think I would say that that side of PMA and the companies I represent strongly endorse this measure, and we would do so even without sections 3 and 4 of the bill, which were added to allay the concerns of the other trade associations. Clearly, we think that with those provisions, the bill should gain wide support. We think you have taken care of all legitimate concerns that might be there, and we urge the adoption.

One last thing, Mr. Chairman. We do recommend that the bill include a provision for reversal of the burden of proof in appropriate situations. That has been discussed by the previous panel, and it is included in my prepared statement, and I will not belabor the point. But we do believe that that would be an improvement in the bill to put the burden on someone who has the ability to determine whether or not the process would infrnge a U.S. patent.

Mr. Chairman, that concludes these brief remarks.

Senator MATHIAS. Thank you very much, Mr. Mossinghoff.

[Mr. Mossinghoff's submissions for the record follow:]

PREPARED STATEMENT OF GERALD J. MOSSINGHOFF

SUMMARY

The Pharmaceutical Manufacturers Association is a national trade association representing 109 research-based pharmaceutical companies. The PMA supports enactment of S.1543, the Process Patent Amendment of 1985. A copier should not be able to circumvent legitimate rights flowing from a process patent simply by practicing the process in a foreign country. This legislation is needed to eliminate a deficiency in our patent law and bring U.S. law into conformity with the patent laws of other major industrialized trading partners.

S.1543 includes limitations which adequately address any legitimate concerns of the generic drug industry, which is the principal group opposed to the bill. The legislation would properly deter a generic company from importing drugs made by the U.S. patented process and force the supplier to switch to an unpatented process. S.1543 is also consistent with the Drug Price Competition and Patent Term Restoration Act of 1984.

The bill should include a provision for reversal of the burden of proof in appropriate situations. A shift in the burden of proof would not create a substantial hardship since the alleged infringer is in a much better position to establish that the product was made by an unpatented process. Such a shift is essential if the process patentee is to have an effective remedy against an importer since the laws of most countries do not have adequate discovery mechanisms of the types sanctioned by United States courts.

* * *

I am Gerald J. Mossinghoff, the President of the Pharmaceutical Manufacturers Association. I am accompanied today by Dr. Alan Lourie, Vice President, Corporate Patents and Trademarks and Associate General Counsel, SmithKline Beckman Corporation, and the Chairman of the PMA Patent Committee.

The PMA is a national trade association representing 109 pharmaceutical companies who are responsible for the vast majority of new drugs introduced in the United States and virtually all pharmaceutical research and development

undertaken in this country. PMA companies rely on the incentives of our patent system in conducting their research and development activities and regularly obtain patent protection on the results of their efforts. S.1543, the Process Patent Amendment of 1985, would strengthen our patent laws by eliminating the opportunity for copiers to avoid infringement of process patents and effectively obtain free use of U.S. research and development expenditures. PMA therefore strongly supports enactment of this legislation. We note that this legislation is also supported by a broad range of companies and industry associations and that the President's Commission on Industrial Competitiveness recommended strengthening of process patents. President Reagan's recently announced set of trade initiatives also cites to the need for better process patent protection.

S. 1543 would amend the patent code to give the owner of a process patent the right to bring an infringement action against someone who uses, sells or imports into the United States a product produced by the patented process. Thus a company would not be able to circumvent legitimate rights flowing from a process patent simply by practicing the process in a foreign country. This amendment is needed to eliminate a deficiency in our patent law and bring U.S. law into conformity with the patent laws of other major industrialized trading partners, including West Germany, France, and the United Kingdom. A provision for protection of the product made by the patented process is also included in the European Patent Convention.

The legislation will generally benefit companies which seek to patent innovative manufacturing processes, including pharmaceutical and chemical companies, and can be expected to have an immediate impact in the emerging field of biotechnology where product patent protection may not be available. Also the legislation should also help preserve domestic jobs since a manufacturer will tend to invest in U.S. manufacturing facilities if patent owners are more fully protected.

The principal oppostion to S.1543 has come from a trade association

representing manufacturers of generic pharmaceuticals. The legislation includes limitations which in our view adequately address any legitimate concerns the generic drug industry may have with this legislation. There is an appropriate provision in the bill which protects the innocent infringer. Also the legislation only applies to products produced or imported after enactment, and there is a grandfather clause to protect those already in substantial and continuous commercial production prior to enactment. The legislation would properly deter generic companies from importing drugs made by the U.S. patented process and force their suppliers to switch to an unpatented process. This should be no great burden since chemical compounds are generally able to be made by any of a variety of processes.

S.1543 is also consistent with the Drug Price Competition and Patent Term Restoration Act of 1984. That legislation facilitates the approval of abbreviated new drug applications at the time of patent expiration. If a patent holder has elected to extend a process patent, the generic copier should not be able to circumvent that patent prior to expiration by having the process performed outside of this country. I should note that a process patent, whether extended or not, will not preclude a generic company from selling a drug whose product patent may have already expired.

The bill should include a provision for reversal of the burden of proof in appropriate situations. We therefore ask that S. 1543 be revised to incorporate Section 295 in H.R. 1069, introduced by Representative Moorhead. A rebuttable presumption should be established in certain instances so that a product that could have been made by a patented process is presumed made by that process. A shift in the burden of proof would not create a substantial hardship since the alleged infringer is in a much better position to establish that the product was made by an unpatented process. Such a shift is essential if the process patentee is to have an effective remedy against an importer since the laws of most countries do not have adequate discovery mechanisms of the types sanctioned by United States courts.

We also recommend some limited revisions to the grandfather provision in Section 3 to clarify that investments must be made in the United States by the person who wishes to import, use or sell the product produced by the patented process outside the United States. We would appreciate the opportunity to assist your staff in developing appropriate language.

This concludes my prepared statement. Dr. Lourie and I appreciate the opportunity to appear before this Subcommittee in support of S. 1543.

RESPONSES BY THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION
TO THE NOVEMBER 15, 1985 QUESTIONS
FROM SENATOR MATHIAS

1. Q. Why is it necessary to hold the purchaser of the foreign product liable under the bill, if he uses or sells it in this country, rather than just targeting the foreign manufacturer who uses the patented process, then exports the product into this country? Why isn't it possible in all these cases to get jurisdiction over the foreign manufacturer, and so cut this activity off at its source?

A. The U.S. purchaser should be held liable because he is the real party in interest in this country who is competing with the patent owner through use of the invention. Since he is not merely an innocent bystander or victim, but is the active competitor, he is in a position to buy or not buy from an infringer and to induce the manufacturer to change his process if he wants the business.

The foreign manufacturer often has no U.S. contacts to make him subject to suit in the U.S. As for suits abroad, the process may not be patented there, or the legal systems may not provide

adequate means for discovery of the infringer's process and properly enforcing the patent.

2. Q. A process patentee bears the burden of proof in ITC proceedings, and in ordinary patent litigation, even if the defendant is an overseas corporation. Why should the burdens be allocated differently in cases arising under this legislation, if enacted?

A. There hasn't been enough process patent litigation in the ITC to indicate that that procedure, leaving the burden of proof on the plaintiff, is or is not effective. It probably wouldn't be, if tested. Reversal of the burden is essential because there needs to be an effective method of resolving the infringement issue.

3. Q. S.1543, in contrast to the bill we considered in the 98th Congress, makes it an infringement to use or sell a product made by an infringement of a patented process in the United States as well as overseas. What practical difference does this addition make? How is the power to sue sellers of domestically-produced products likely to be used?

A. There may be little practical difference, but it makes no sense conceptually to give a product of a patented process protection only when made abroad, but not when made in the U.S. If a product of a patented process is to be protected, its place of origin should not matter. It doesn't in the laws of other countries. Sellers of domestically-produced products are not likely to be sued because they are not the parties the patentee wishes to stop. The entity that practices the process in the United States will be sued for infringement.

4. Q. What is likely to be the impact of this legislation on jobs

here in the United States? As you know, the generic drug industry has argued that providing this protection would eliminate the incentive that exists under the ITC remedy to maintain manufacturing operations in this country. The ITC remedy requires a showing of injury to an efficiently run domestic industry. But if process patent protection were unavailable under our patent laws, the generic companies argue, it would no longer be a requirement that the patent holder was manufacturing with his process in this country, and so he would probably shift his operations overseas to realize other economic advantages such as cheaper labor. How would you rebutt this analysis?

A. The impact of this legislation on jobs in the U.S. is likely to be positive. Instead of having bulk chemical produced abroad by infringers, it might be produced here by the patent owner or his licensee. The ITC remedy doesn't really affect decisions to manufacture in the U.S. or abroad. Those decisions are based on availability of plants and manpower, location of markets, tax incentives, existence of enforceable patent protection, etc. The argument that a new process patent law would eliminate the incentive for a patentee to manufacture here makes no sense because the whole purpose of the law is to stop infringing foreign manufacturers. American drug manufacturers have a variety of factors to consider in choosing manufacturing sites including those enumerated above and the threats of foreign governments to exclude products if the company doesn't manufacture there. Even if the company manufactured abroad, that would be no worse than what the infringers are doing. Ultimately, whether a U.S. company manufactures in the U.S. or not is not determined by the present provisions of the Trade Act and will not be much affected by the process patent law.

5. Q. The Commissioner of Patents testified that S.1543 should be

amended to clarify that it applies only to products directly produced by the patented process. Do you have any comments on this suggestion?

A. This suggestion has merit. Other national laws have the same limitation and, in the interest of clarity, it is important that a company know whether its noninfringing activity in one country could become an infringement in the U.S. A limitation in the bill by the use of the term "directly" so that importation and sale only infringe a patent claiming the last main step of the process used in manufacture could achieve that objective. If such an amendment is adopted, the legislative history should state that immaterial and minor later steps such as salt formation or removal of protective steps should not be construed in such a way that importation of the final product of that added step would not be an infringement. In other words, if the B-to-C step is chemically trivial, C would still be the direct product of the patented process A-to-B, whereas, if B-to-C is material and not chemically trivial, then C would not be directly produced by the process A-to-B and would not infringe a patent claiming A-to-B. Without this limitation, carrying out the step A-to-B in one country could result in compound G, six steps away from the patented process, being considered an infringement.

6. Q. The representative of the National Chain Drug Store Association, suggested that attorney fees should be awarded to the defendant if the plaintiff loses in a case brought under the bill (even if it was brought in good faith). What is your reaction to this suggestion? What, in your view would a successful defendant have to show under the existing law of attorneys' fees to make out a claim of entitlement to attorneys' fees in a case brought under this legislation, if enacted as introduced?

A. There is almost no chance a retailer would be sued by a drug

company under a process patent. The patentee would sue the manufacturer of the dosage form whose name is on the product and who is the real party in interest. Moreover, it would be bad law to assess attorneys' fees on any plaintiff who brings a suit in good faith. It should be recognized that the theoretical problem faced by a retailer is no different from what he faces now under a product patent and under a process patent when the process is carried out in the U.S. They don't get sued now and they aren't likely to be sued if this bill passes. The difficulty of learning what process is used in the manufacture of the product really doesn't add to their problems, because, even now, they don't know the patent status of a product or the details of a manufacturing process that may have been used in the U.S.

Under existing law, a successful defendant would need to show inequitable conduct in the procurement of the patent or a reckless failure to investigate the facts before suing in order to be assessed attorneys' fees.

Senator MATHIAS. Dr. Ostro.

STATEMENT OF MARC J. OSTRO

Dr. OSTRO. Thank you, Senator, for inviting me here to represent the Liposome Co., specifically, and the biotechnology industry in general.

We think we have somewhat of a different kind of story to tell as it relates to this bill. We are a 4½-year-old biotechnology company whose focus is to develop novel drug delivery systems made of liposomes—and since time does not allow, I will not go into a detailed explanation of what liposomes are.

The idea to form the Liposome Co. goes back to the early part of 1980 when a group of venture capitalists, most notably Jack Whitehead of Whitehead Associates, and the International Nickel Co.'s

Venture Capital Division, agreed to finance the Liposome Co. with seed money.

Literally, the company started in my living room—I know that is an old saying, but it is true in this case. We went from the position of having me as the only employee to a point where we now we employ 63 people and have commitments to hire an additional group, raising our number to 75 by the end of 1986.

I can say with a high level of certainty that had it not been for protective patent legislation in our industry, the opportunity for the growth that I have just described certainly would not exist.

This technology has been extensively studied in universities over the last 20 years. It has yet to be commercialized, but it certainly has been well studied. As a result there is a considerable amount of prior art in the public domain which makes product patents very difficult for us to obtain. In spite of this difficulty, we filed 35 patent applications, at a cost of over $1 million. This is a considerable sum for a very small company. Since we are a venture capital-backed firm and do not yet have revenue from product sales, the $1 million spent on filing of patent applications does represent a considerable financial commitment. But these patents are, in essence, our early products. That is to say, we and other biotechnology companies similar to us have been able to raise substantial sums of money from private investors as well as large pharmaceutical companies by selling rights to use selective parts of our patent inventory.

It is this money that will have allowed us to create, by the end of 1986, 75 new jobs in New Jersey. I think it is fair to say that if we cannot protect the subject matter covered by these patents, we will be unable to bridge the financial gap between where we are now and our projected date for the introduction of our first pharmaceutical products.

I could give you several examples of how this bill would strengthen our position, but since time is short, I think I will end by saying that we also would encourage the committee to consider reinstating provisions for the reversal of the presumption of noninfringement.

Thank you.

Senator MATHIAS. Thank you very much, Dr. Ostro.

[Mr. Ostro's submissions for the record follow:]

Prepared Statement of Marc J. Ostro

My name is Dr. Marc Ostro and I am here oday to testify in favor of Senate Bill 1543 to protect patent owners from the importation of goods made overseas by use of a U.S. patented process.

I am Vice Chairman and Chief Science Officer of The Liposome Company (TLC) which is located in Princeton, New Jersey. We are a 4 1/2 year old biotechnology company whose focus is to develop novel drug delivery systems made from liposomes. The idea to form TLC goes back to the early part of 1980 when a group of venture capitalists headed by Jack Whitehead of Whitehead Associates and the International Nickel Company's Venture Capital Division agreed to put up seed money to finance the commercialization of liposome technology. Literally this company started in my living room, and in the 4 1/2 years that we have officially been in existence we have grown from a single employee to 63 and have hiring commitments to raise our employee number to 75 before the end of 1986.

I can say with a high level of conviction that had it not been for protective patent legislation the opportunity for such rapid growth would not exist. However, before I more fully explain the importance of patents in general and method patents in particular to TLC, I feel I should explain what a liposome is. Briefly, liposomes are microscopic balloons whose membrane is composed of naturally occurring fats. Within these balloons we can place a wide variety of drugs, and by properly engineering the membranes we can among other things reduce toxicity of anticancer drugs, improve the efficacy of a wide variety of antibiotics and create a broad array of long-acting medications.

Since this technology has been extensively studied in university environments over the last 20 years (they were first produced by Alec Bangham, a British scientist, in 1965), there is a considerable amount of

prior art in the public domain which in many cases makes product patents difficult to obtain. In spite of this difficulty we have filed 35 patent applications at a cost in excess of $1 million covering procedures to produce liposomes, the liposomes themselves, and the use of this technology to combat a variety of diseases.

Since we are a venture capital backed firm and do not yet have revenue from product sales, the $1 million spent on the filing of patent applications represents a considerable financial commitment for a small company. But in essence, these patent applications represent our current products. That is to say, we and other biotechnology companies similar to us have been able to raise substantial sums of money from private investors as well as large pharmaceutical companies by selling rights to use selected parts of our patent inventory. It is this money that will have allowed us to create by the end of 1986 75 new jobs in New Jersey. I think it is fair to say that if we cannot protect the subject matter covered by these patents, we will be unable to bridge the financial gap between where we are now and our projected date for the introduction of our first pharmaceutical products.

Let me illustrate this point by giving an example. The basic raw material needed to produce liposomes is a chemical called lecithin derived from egg yolks and soy beans. When TLC was started, one kilogram of 99% pure egg lecithin would cost approximately $20,000. At that cost no liposome-based pharmaceutical product would ever be commercializable since the wrapper of the drug would cost, in some cases, as much as 100 times more than the drug itself. We have devoted 4 1/2 years and several million dollars to devise a process whereby we can now produce the same egg lecithin for as little as $200 a kilogram.

It is our conviction as well as the belief of a growing list of large companies that liposome-based products will make a substantial impact on the pharmaceutical industry. All the pharmaceutical companies

producing liposome-based products will need this vital raw material. We therefore feel that its sale represents a significant commercial opportunity for us. If foreign competitors using the same process were able to import 99% pure lecithin into the U.S. at comparable prices, our investment of time and money would have gone for naught. As a small company, such a set of circumstances would dramatically reduce our rate of progress towards reaching our goal of profitability. If such an infringement were to occur under Title 19, our remedies would be limited.

If we are to foster growth in our country and encourage venture capitalists and pharmaceutical companies to invest in new technologies, it is imperative that we prevent foreign companies from squeezing out and destroying the chances for small U.S. industries to develop to their full potential. Foreign competitors should not have an unfair advantage in competing with U.S. companies because of their freedom from our patent laws.

As a result of the existing loophole addressed by this Bill, foreign competitors who have made no investment in research and have taken none of the risks in developing a new technology can reap the rewards of our efforts. We feel that this Bill is an important step in closing this loophole. In fact, we feel that the Bill should go further than currently proposed by adequately addressing the difficulties in discovery when foreign defendents are involved. We would therefore encourage the Committee to consider reinstating provisions for the reversal of the presumption of noninfringement.

Responses of Marc J. Ostro to Written Questions of Senator Mathias

(1) Why is it necessary to hold the purchaser of the foreign product liable under the bill, if he uses or sells it in this country, rather than just targeting the foreign manufacturer who uses the patented process, then exports the product into this country? Why isn't it possible in all these cases to get jurisdiction over the foreign manufacturer, and so cut this activity off at its source?

(2) A process patentee bears the burden of proof in ITC proceedings, and in ordinary patent litigation, even if the defendant is an overseas corporation. Why should the burdens be allocated differently in cases arising under this legislation, if enacted?

(3) S. 1543, in contrast to the bill we considered in the 98th Congress, makes it an infringement to use or sell a product made by an infringement of a patented process in the United States as well as overseas. What practical difference does this addition make? How is the power to sue sellers of domestically-produced products likely to be used?

(4) What is likely to be the impact of this legislation on jobs here in the United States? As you know, the generic drug industry has argued that providing this protection would eliminate the incentive that exists under the ITC remedy to maintain manufacturing operations in this country. The ITC remedy requires a showing of injury to an efficiently run domestic industry. But if process patent protection were unavailable under our patent laws, the generic companies argue, it would no longer be a requirement that the patentholder was manufacturing with his process in this country, and so he would probably shift his operations overseas to realize other economic advantages such as cheaper labor. How would you rebut this analysis?

(5) The Commissioner of Patents testified that S. 1543 should be amended to clarify that it applies only to products directly produced by the patented process. Do you have any comments on this suggestion?

(6) The representative of the National Chain Drug Store Association, suggested that attorney fees should be awarded to the defendent if the plaintiff loses in a case brought under the bill (even if it was brought in good faith). What is your reaction to this susggestion? What, in your view, would a successful defendant have to show under the existing law of attorneys' fees to make out a claim of entitlement to attorneys' fees in a case brought under this legislation, if enacted as introduced?

1. (a) It is often difficult to establish the source of a product imported into this country. One who imports products for use or resale is in a better position to bring economic pressure on the foreign manufacturers to obtain the necessary information regarding the process.

(b) Often a foreign manufacturer does not have sufficient contacts in this country to establish personal jurisdiction. In addition, since the acts of the manufacturer are done overseas, the new cause of action

for infringing a process patent outside the U.S. in the proposed legislation is needed to establish subject matter jurisdiction.

2. Under an ITC proceeding, the remedy is limited to an exclusive order. The difficulty in establishing use of a process patent is in fact a difficulty in actions brought before the ITC. Because it is difficult or impossible to obtain the necessary discovery for overseas corporations, it is often impossible to show which processes the overseas corporation is employing. By reversing the burden of proof, a fairer situation will occur, the party having the information will be required to make such information available.

3. (a) It is generally rare for infringement actions to be brought against the ultimate consumer of a product. However, in certain instances, such actions are employed for patented products. The extension of the law to cover the use and sale of products made by a patented process only corrects a loophole which penalizes certain inventions. Under the bill, an infringer of a process patent can be reached by means of the users and sellers of the product.

(b) In the vast number of cases the additional power to bring in the seller will have little practical effect since the manufacturer is the primary target of virtually all infringement litigations. In those instances where the sellers are knowingly promoting the use of infringing products, this bill will afford an effective remedy for such practices.

4. (a) It is likely that many more jobs will be created in the United States as a result of this legislation. An important economic advantage of producing goods overseas and importing them to the United States will be lost.

(b) There are at least three flaws in the argument of the generic drug industry. First, it is the practice of the generic drug industry to import bulk quantities of drugs which are manufactured outside the United States. It is therefore in their own interest to not enact the current bill. Their analysis fails to include the amount of research and development dollars spent in the United States to bring a new drug to market. An incentive to spend the $80 to 100 million needed for the average new drug is the exclusivity afforded under our patent laws. This protection includes both product and process patents. An incentive to attempt to lower prices through developing more efficient processes is the ability to exclude others from using these processes. Under the present loopholes there is little incentive to develop patentable processes if the fruits of this research effort can be used by overseas manufacturers.

One of the reasons manufacturing occurs overseas is the inability of domestic innovators to exclude other foreign manufacturers. Strengthening the patent position of domestic innovators will enable them to make the inventions necessary to produce in the United States. Technology can then be used to overcome cheap foreign labor.

5. There is a complex number of steps needed to produce many high technology products including electronics, communications and pharmaceutical products. Under our current patent laws, downstream users of a product which results from an infringed process are generally insulated from prosecution. In addition, it would make little economic sense to sue a multitude of users far removed from the point in the chain from which the infringement occurred. The only practical way to prevent infringement is to attack the manufacturers either under the proposed bill or by an ITC hearing.

6. (a) The purpose of the patent law is to protect and reward innovators. The NCDSA proposal would have a chilling effect upon a patentee ensuing a potential infringer. Under the present law there are already sufficient penalties if a suit is brought frivolously or in bad faith.

(b) Under the current law a defendent is entitled to attorneys fees in exceptional cases. Exceptional cases include those wherein the patent was fraudulently obtained, the lawsuit was frivolously brought, the patentee knew there was no infringement by the defendent or the suit was brought for economic reasons other than infringement. The courts have had little difficulty to date in recognizing exceptional cases and punishing the patentee accordingly.

Senator MATHIAS. Mr. Massengill.

STATEMENT OF ROY H. MASSENGILL

Mr. MASSENGILL. Thank you, Mr. Chairman.

I appreciate the opportunity to appear today on behalf of Allied-Signal, Inc. I wish to thank the chairman and Senator Lautenberg and your colleagues for introducing S. 1543.

I would like to make three points today.

First, process patents are very critical to the advancement of technology in the United States. Second, foreign producers are appropriating American technology through unauthorized use of our patented processes. Lastly, this legislation, along with amendments to our trade laws, is necessary to protect American technology, American industrial growth, and American jobs.

The recent merger of Allied Corp. and the Signal Companies to form Allied-Signal, Inc., created one of the largest high-technology corporations in the world, with annual expenditures for research and development and engineering of over $1 billion, in such diverse fields as strategic materials, aerospace, biotechnology, and electro-optics.

We received nearly 600 U.S. patents in 1984. Worldwide, Allied-Signal has more than 35,000 patents granted or pending, and nearly one-half are process patents.

Process patents are being used to improve the economic efficiency of existing industries, and they will be the key to many of tomorrow's new products.

Our foreign competitors are well aware of the importance of process technology and the patents which protect them. They are also aware that if they make an unpatented product not protected by a patent in the United States and use one of our patented processes abroad, they can sell that product in the United States without violation of our U.S. patent law.

I would like to relate one of our own experiences for you. Allied Corp. developed a process for the manufacture of an amorphous metal strip, which is a thin metal film having a random molecular structure more typical of glass than metal, which exhibits extraordinary properties. Amorphous metals are harder, stronger, and more corrosion-resistant than stainless steel. They are more easily magnetized than any other known material. Application for amorphous metals ranges from the substitution of gold in brazing jet engine components, which eliminates the need to use a precious metal, to the magnetic core materials of utility transformers, which reduces power losses up to 75 percent or more. Allied has spent over $75 million and over 13 years in the development of amorphous metal technology. We believe it will be key to the estab-

lishment of an entire new industry in the United States. There are estimates that this technology will support a billion-dollar business in the foreseeable future. A significant portion of this technology is process technology, and it is protected by process patents. A basic process patent was applied for in 1976 and granted in 1980 in the United States. We applied for corresponding process patents in Germany and Japan in 1977. The German patent was granted earlier this year, but it has been opposed by our competitors. In Japan, the patent is still pending in their patent office. While these patents have been delayed in their patent offices, Japanese and German companies have been using our process in their countries to manufacture amorphous metal strips and ship the product into the United States.

We recently obtained an exclusion order from the ITC, but that is not a complete remedy, and I do not have the time to go into the reasons why; they have been amply stated here this morning. But I think that our example is one that is indicative of what is happening in U.S. industries today regarding the shipment of products into this country that are made abroad by U.S. patented processes.

Therefore, Allied-Signal urges this committee to pass this legislation, S. 1543, as soon as possible.

Thank you.

Senator MATHIAS. Thank you very much.

[Mr. Massengill's submissions for the record follow:]

PREPARED STATEMENT OF ROY H. MASSENGILL

INTRODUCTION

I am Roy H. Massengill, General Patent Counsel for Allied Corporation. I appreciate this opportunity to appear today and wish to thank Chairman Mathias, Senator Lautenburg and their co-sponsors for the introduction of S. 1543, a bill to provide protection for process patents against foreign infringement.

I would like to make three points:

First, process patents are critical to the advancement of technology in the United States;

Second, foreign producers are appropriating American technology through unauthorized use of our patented processes; and

Finally, this legislation, along with amendments to our trade laws, is necessary to protect American technology, American industrial growth and American jobs.

THE ROLE OF PROCESS PATENTS

The recent combination of Allied Corporation and the Signal Companies has created one of the largest high technology corporations in the world with annual expenditures for research, development and engineering of over a billion dollars in such diverse fields as strategic materials, aerospace, biotechnology, and electro-optics. We received nearly 600 U.S. patents in 1984. Worldwide, Allied-Signal has more than 35,000

patents granted or pending; and, nearly one-half are process patents.

Some of the most important technological breakthroughs in the chemical and drug industries have resulted from the discovery of new process technology. Process patents are also key to many other businesses. Process patents protect the development of new strategic materials, laser, fiber optics and computer technology. And process patents, in particular, protect the fledgling biotechnology industry. For example, naturally occurring materials such as insulin cannot be patented; however, one can patent processes for making such materials.

Process patents are being used to improve the economic efficiency of existing industries, and they will be the key to many of tomorrow's new products.

THE THREAT

Our foreign competitors are aware of the importance of process technology and the patents which protect them. They are also aware that if they make an unpatented product not protected by a patent in the U.S. and use one of our patented processes abroad, they can sell that product in the United States without violating our U.S. patent law.

I will relate our own experience. Allied Corpation developed a process for the manufacture of amorphous metal strip, a thin metal film having a random molecular structure more typical of glass than metal which exhibts extraordinary properties. Amorphous metals are harder, stronger and more corrosion resistant than stainless steel. They are more easily magnetized than any other known material. Applications for amorphous metals range from the substitution of gold in brazing

jet engine components, thereby eliminating the need to use a precious metal, to the magnetic core materials of utility transformers, thereby reducing power losses up to seventy-five percent or more. Allied has spent over $75 million and thirteen years developing amorphous metals technology, and we believe it will be key to the establishment of an entire new industry in the United States. There are estimates that this technology will support a billion dollar business in the foreseeable future. A significant portion of this technology is process technology and it is protected by process patents.

Our basic process patent was applied for in the U.S. in 1976 and granted in 1980. We applied for corresponding process patents in Japan and Germany in 1977. The German patent was granted earlier this year, but it has been opposed by foreign competitors. In Japan, the patent is still pending in their patent office. While these patents have been delayed in their patent offices, Japanese and German companies have been using our process in Japan and Germany to manufacture amorphous metal strip and ship product into the United States.

Since there was no process patent protection under U.S. patent law, Allied initiated an action under Section 337 of the Trade Act before the International Trade Commission against these Japanese and German competitors in 1983. Ultimately, the ITC found that eleven companies had engaged in unfair trade practices as a result of their use of our patented process abroad. A general exclusion order was issued by the ITC and approved by the President.

We were very fortunate to obtain that exclusion order since one of the deficiencies of the Trade Act is that a U.S. company must show injury to an existing industry. Fortunately, we had sold product and were able to prove injury. However, a process

patent will often be the basis for a business in its infancy - one which is in the tenuous first days of its life with little or no sales. If its patented process technology is appropriated abroad, that new business may never develop in the United States. The domestic practice of high technology has been stifled in its inception and a clear disincentive to investment in high technology has been established. Senate Bill 1543 would remedy this deficiency since it contains no requirement of injury to an industry.

A second deficiency in the Trade Act is the inability of the Commission to award damages for the unauthorized use of patented process technology. Only injunctive relief preventing future activity is available under Section 337. No monetary damages are available. Thus, infringers are given a free ride until an exclusion order issues. That is because, even if they lose before the ITC, they are able to keep their profits while the litigation is pending. Those who argue that Section 337 is an adequate remedy do a gross disservice to American industry. Section 337 may let you win eventually; but there is no disincentive to foreign infringers in the meantime and this leads to a loss in domestic jobs and injury to the economy.

THE SOLUTION

Today, when we hear so much about the trade deficit and the loss of jobs to foreign competition, it seems to me the least we can do is protect the fruits of our own research and development - the tools which produce greater efficiency and competitiveness.

We must provide our process patents protection essentially on a par with that offered by our major trading partners - Japan, West Germany, France and the United Kingdom.

The very least we can do is prevent foreign competition from using our patented processes without permission to make products for sale in the United States in competition with our own products. Allied-Signal urges the swift passage of S.1543.

And, although it is not within the jurisdiction of this Subcommittee, we would also urge each of you individually to support legislation which would amend the Trade Act as has been provided in S.1647, introduced by Senators Lautenberg and Roth. However, passage of S.1543, the subject of today's hearings, is essential regardless of whether or not the Congress amends the Trade Act.

Thank you Mr. Chairman. I would be pleased to answer any questions the Committee or its staff may have.

Responses of Roy H. Massengill to Written Questions of Senator Mathias

Question 1:

Why is it necessary to hold the purchaser of the foreign product liable under the bill, if he uses or sells it in this country, rather than just targeting the foreign manufacturer who uses the patented process, then exports the product into this country? Why isn't it possible in all these cases to get jurisdiction over the foreign manufacturer, and so cut this activity off at its source?

Reply 1:

The U.S. patent laws should be amended to achieve conformity with the patent laws in major foreign industrial countries. Patent owners in such countries may bring infringement actions against purchasers of foreign-produced products. Moreover, there are many procedural and practical complexities in obtaining jurisdiction and adjudicating matters against foreign manufacturers. Enforcing judgments could prove to be futile.

Question 2:

A process patentee bears the burden of proof in ITC proceedings, and in ordinary patent litigation, even if the defendant is an overseas corporation. Why should the burdens be allocated differently in cases arising under this legislation, if enacted?

Reply 2:

The burden of proof would be the same where the overseas manufacturer is subject to discovery to the same extent as a U.S. manufacturer. The shift in burden of proof is essential after diligent efforts have been exhausted by the patentee and the overseas manufacturer "stonewalls" discovery efforts by the patentee. In such situations the patent laws should permit the Courts to draw inferences and issue sanctions.

Question 3:

S.1543, in contrast to the bill we considered in the 98th Congress, makes it an infringement to use or sell a product made by an infringement of a patented process in the United States as well as overseas. What practical difference does this addition make? How is the power to sue sellers of domestically-produced products likely to be used?

Reply 3:

This change would strengthen and enhance the U.S. patent laws. However, as a practical matter the owner of a process patent is not interested in bringing a multiplicity of litigations where it is possible to bring a single litigation to obtain the same result. I do not think this power will be used except in instances where the manufacturer has insulated itself in some way from a successful suit. It is my understanding that the application to domestically produced products was primarily intended to resolve a perceived problem under the General Agreement on Tariffs and Trade.

Question 4:

What is likely to be the impact of this legislation on jobs here in the United States. As you know, the generic drug industry has argued that providing this protection would eliminate the incentive that exists under the ITC remedy to maintain manufacturing operations in this country. The ITC remedy requires a showing of injury to an efficiently run

domestic industry. Buf if process patent protection were unavailable under our patent laws, the generic companies argue, it would no longer be a requirement that the patentholder was manufacturing with his process in this country, and so he would probably shift his operations overseas to realize other economic advantages such as cheaper labor. How would you rebut this analysis?

Reply 4:

U.S. manufacturers have a strong preference for manufacturing their products in the U.S. They manufacture abroad in most instances only because of some compelling economic reason. The solution is to provide the U.S. manufacturers with legal protection against overseas pirates and they will manufacture their products in the U.S. We are not dealing with commodity products where cheap labor costs are a significant factor. Products made by patented proprietary processes are not economically dependent upon cheap labor, absent unfair trade practices.

Question 5:

The Commissioner of Patents testified that S.1543 should be amended to clarify that it applies only to products directly produced by the patented process. Do you have any comments on this suggestion?

Reply 5:

Limitation of S.1543 to products directly produced by the patented process would inject uncertainty into the statute. Would trivial aftertreatment or minor modification of the product remove it from the ambit of the statute? I would hope not. The appropriate degree of directness will be extremely difficult to define. My inclination is to not include it, but that, if it is, the legislative history should define "directly" so as to avoid minor modification of aftertreatment of the product.

Question 6:

The representative of the National Chain Drug Store Association suggested that attorney fees should be awarded to the defendant if the plaintiff loses in a case brought under the bill (even if it was brought in good faith). What is your reaction to this suggestion? What, in your view, would a successful defendant have to show under the existing law of attorneys' fees to make

out a claim of entitlement to attorneys' fees in a case brought under this legislation, if enacted as introduced?

Reply 6:

The present statutory provision on attorney fees, 35 USC 285, is adequate to redress any misuse under this legislation. I oppose the award of attorney fees to a prevailing defendant as a matter of course since (1) a prevailing plaintiff would not be entitled to a similar award and (2) the treatment would be inconsistent with current law requiring exceptional circumstances, such as lack of good faith. The issues here are no different from other litigation matters regarding abuse of legal process.

Senator MATHIAS. Mr. Hancock.

STATEMENT OF NOLAN W. HANCOCK

Mr. HANCOCK. Thank you, Mr. Chairman, for allowing OCAW the opportunity to testify here today regarding our views concerning S. 1543.

This bill would protect patent owners from the importation into the United States of goods made abroad in violation of U.S. process patents. U.S. law should not foster and support the manufacture and importation of foreign goods utilizing cheaper labor and industries subsidized by foreign governments in direct competition with the same products made in the United States which, if made in the United States by a competitor, would violate the law.

In other words, it is OK for a foreign manufacturer to do something which U.S. manufacturers could not do. And this is a question of fairness, Mr. Chairman.

The members of this subcommittee are well aware of the staggering number of manufacturing jobs lost to American workers every day, jobs which probably will never return to the United States. Over the past 5 years in my union alone, Mr. Chairman, we have lost 50,000 members. There are many reasons why this is happening. But we should also include in solving the problem the passage of legislation that would provide for adequate protection in the U.S. patent laws for the process technology from foreign firms that engage in pirating process patents of U.S. manufacturers.

Inventions and processes resulting in U.S. technology patents are not only the creation of a few scientists and technicians, but they are also the result of knowledge and dedication of American workers and craftsmen working along with scientists to create entirely new processes that will improve America's competitiveness throughout the world. When such U.S. patented processes are stolen and infringed upon by foreign entrepreneurs, the American worker is both cheated and robbed, not only of his work but of a just inheritance for his children and the company he works for and the community where the plant is located.

The lack of effective patent protection for processes amounts to a loophole in the U.S. patent law which currently allows foreign manufacturers to circumvent a U.S. patent when it covers a process rather than a product.

We need legislation that will protect U.S. companies from unfair competition from foreign manufacturers who are in effect taking a free ride on U.S. research and development expenditures by reaping the profits at no research and development cost. If the rights of U.S. patent owners are protected, these owners are more likely to invest in preserving jobs for American workers.

We believe that the passage of S. 1543 would protect patent owners from goods made abroad using processes patented in the United States and help in preserving and recovering jobs. This legislation would allow domestic parties to bring action in U.S. district court in order to block the importation of such products. It seems to us that giving this added protection to U.S. patent owners will encourage manufacturing in the United States by providing protection to the inventor and the company who invests in the research and development. As we understand it, America's major trading partners already have provisions similar to S. 1543 in the patent laws of their countries. There is no reason for the United States not to have the same protection in its patent law.

This legislation would put the U.S. patent law essentially on par with the patent laws of Japan, West Germany, France, and the United Kingdom. We would urge the support of this committee for passage of S. 1543. Your support and efforts on behalf of this legislation will be appreciated by the American worker in all of the industries developing new technologies and new processes.

Thank you, Mr. Chairman.

Senator MATHIAS. Thank you, Mr. Hancock.

[Mr. Hancock's prepared statement follows:]

PREPARED STATEMENT OF NOLAN W. HANCOCK

ON BEHALF OF THE

OIL, CHEMICAL AND ATOMIC WORKERS INTERNATIONAL UNION

Mr. Chairman and members of the Subcommittee, my name is Nolan W. Hancock. I am Citizenship-Legislative Director for the Oil, Chemical and Atomic Workers International Union. OCAW is the primary representative of workers employed in the chemical, energy and fuel producing industries, with a total membership exceeding 120,000 members in 48 states. We are also a primary representative of workers employed in the drug industry.

I wish to thank the Chairman for allowing OCAW the opportunity to testify today, so that we may express our views concerning S-1543. This bill would protect patent owners from importation into the United States, of goods made abroad in violation of U.S. process patents.

Current law prohibits the manufacture, use or sale of a product in the U.S. in violation of a U.S. patent. It does not, however, prohibit the importation of a product made in a foreign country in violation of a U.S. patent, nor does it prohibit the use or sale of a product in the U.S. produced abroad in violation of a U.S. process patent. The exception to this is Section 337 under the International Trade Commission Act. S-1543 would eliminate this anomoly in the U.S. law by giving U.S. process patent owners the right to bring a suit for patent infringement against a party who uses, sells or imports a product made abroad using a U.S. patented process. However, the bill provides a grandfather clause for current manufacturers or retailers of current products. It also will not affect any innocent purchasers of manufactured products who had no knowledge of the infringement. It is the union's intent in this legislation to stop foreign processing of material in violation of U.S. patents. We do not intend that it be a vehicle for the prosecution of pharmacists and other retailers. This issue is basically a question of fairness.

U.S. law should not foster and support the manufacture and importation of foreign made goods utilizing cheaper labor in industries subsidized by foreign

governments in direct competition with the same products made in the U.S. which if made in the U.S. by a competitor, would violate the law. In other words, it's okay for foreign manufacturers to do something which U.S. manufacturers could not do. This is not fair.

The members of this Subcommittee are well aware of the staggering number of manufacturing jobs being lost to American workers every year — jobs which will probably never return to the U.S. During the past 5 years more than 50,000 OCAW members have lost their jobs. There are many reasons why this is happening — the high value of the dollar, low-wage imports, unfair subsidized foreign imports, unfair trade laws abroad and obsolete American manufacturing capabilities in smokestack industries. We should also include the inadequate protection in U.S. patent law for process technology from foreign firms that engage in pirating process patents of U.S. manufacturers.

Inventions and processes resulting in new U.S. technology patents are not only the creation of a few scientists and technicians hidden away in small laboratories. They also result from the knowledge and dedication of American workers and craftsmen working with the scientists to create entirely new processes that will improve America's competitiveness throughout the world. When such U.S. patented processes are stolen and infringed upon by foreign entrepreneurs, the American worker is both cheated and robbed not only of his work, but of a just inheritance to his children, the company he works for, and the community where the plant is located.

The lack of effective patent protection for processes amounts to a loophole in the U.S. patent law which currently allows foreign manufacturers to circumvent a U.S. patent when it covers a process rather than a product. This happens because a product patent is infringed whenever the product is made, sold or used in the U.S., but a process patent is infringed only if the manufacturing is done in the U.S.

We need legislation that will protect U.S. companies from unfair competition by foreign manufacturers who are in effect taking a free ride on U.S. research and development expenditures, by reaping the profits at no research and development costs. If the rights of U.S. patent owners are protected, these owners are more likely to invest in manufacturing facilities located in the United States, thus preserving jobs for American workers.

Also, effective protection for owners of U.S. process patents is important to foster a climate which will encourage U.S. companies to invest in additional research and development in the future.

Such legislation is important in two other respects — it will benefit the emerging biotechnology industry in America since often the only protection available in the biotechnology field is a process patent, and secondly, it could provide an adequate remedy for damages to process patent owners against the foreign infringers. At the present time, the only remedy for preventing goods manufactured in a foreign country by a process protected by a U.S. patent from entering the U.S. is the inadequate and complex remedy under Section 337 of the International Trade Commission Act.

Americans are famous for "yankee ingenuity". Too often, however, we hear of instances where an American invention is taken abroad and the manufacturers and workers in other countries profit from it.

America's inventiveness, if given adequate legal protection, can help us recover some of the manufacturing jobs lost in this country. The industries in which our members are employed, such as the pharmaceutical and petrochemical industries rely heavily on patented technology. America will continue to have an advantage in these technologies only if its intellectual property is effectively protected.

We believe the passage of S-1543 would protect patent owners from goods made abroad using processes patented in the U.S., and help in preserving and recovering jobs.

This legislation would allow domestic parties to bring actions in U.S. District Court in order to block the importation of such products.

It seems to us that giving this added protection to U.S. patent owners will encourage manufacturing in the United States by providing protection to the inventor and/or company who invests in research and development.

As we understand it, America's major trading partners already have provisions similar to S-1543 in the patent laws of their countries. There is no reason for the United States not to have the same protection in its patent law.

This legislation would put the U.S. patent law essentially on a par with the patent laws of Japan, West Germany, France and the United Kingdom.

We would urge the support of this Committee for passage of S-1543, "the Process Patent Amendment of 1985." Your support and efforts on behalf of this legislation will be appreciated by American workers in all industries developing new technology and new processes.

Thank you very much.

Senator MATHIAS. As all of you know, the Congress in enacting legislation has to weigh the impact on all sides. We have to listen to your case, and we have to listen to the case of the people who may feel differently. I myself have used the word "loophole"; Mr. Banner used the word "loophole," but as he did so, I had to reflect that what you consider to be a loophole, somebody else may consider to be free enterprise. It does not always operate equally on all parties.

Do you see, in the light of your knowledge of how the intellectual property laws work, that there is a case to be made for those who will say we are restricting free enterprise by this bill?

Mr. BANNER. Senator, having been a lawyer for a great many years, it would be fair to say that I think you could make a case for almost everything. Whether it is a good case is a different story.

The issue of a loophole, I think, must be considered in the context of the world we live in. The loophole that I am talking about is the one that is in our law, and it does not happen to be in the law of our trading partners. They have blocked that loophole, and we have not. And I think we are standing out there in the cold looking a little stupid, frankly.

Senator MATHIAS. Why is it that other countries have blocked this loophole and that we have not? There are, of course, different versions of this story. Some countries do not allow process patent protection; some are slow to approve; some just do it bureaucratically by being slow in the process, just not shuffling the papers very fast. It is a little like our friends in France who control imports by having only one small customhouse in Poitier, through which all goods must pass, and that does discourage importing.

But can you shed some light on just why there is a difference in international practice?

Mr. BANNER. I think that there are many different reasons, and I certainly could not speak to the matter in a generic way today—if I can use that expression. But the fact of the matter is, I think, in our own country, historically, we have not been bothered very much about import problems until recent years. We have not been bothered in modern times with these issues until now. We suddenly find ourselves in the horrendous position of having an incredible trade deficit, incredible in comparison with what happened a few years back, and also having people become unemployed because of competition from other countries. This is a relatively new phenomenon and we are now seriously becoming interested in its impact for the first time.

Senator MATHIAS. Mr. Mossinghoff, if you could hold your response. As the veterans here know, those bells mean that there is a vote on the floor. I had hoped we might get through this panel, but I can see we will not, so I will have to ask you to wait, if you will, and I will go vote and be back just as quickly as possible.

The committee will stand in recess.

[Short recess.]

Senator MATHIAS. When the voting bells rang, I think Mr. Mossinghoff was just about ready to utter a profound thought.

Mr. MOSSINGHOFF. Or at least a thought, Mr. Chairman.

I was going to say that I think that the fact that the European countries particularly have this, at least in our industry, may stem

from the fact that for a while, countries did not have product protection for chemicals and pharmaceuticals. When that is the case, then process patents become extremely important, and you could imagine that the industrial sources would prevail upon their parliaments or legislatures to protect the process patents.

Since then, most or virtually all of the European countries, the OECD countries, do now have product protection for pharmaceuticals and chemicals, and we are using that as a worldwide standard. We really think that that is an important thing to do worldwide.

In the United States, our member companies typically will seek, and in many cases successfully, product protection, so the issue of process patents was not foremost, or was not on the front burner. With the emergence of biotechnology, where existing products that occur in nature can be made through biotechnology, process patents do become a lot more important to that segment of our industry. To put in context our position, we strongly support this, and if an example is needed it is because of the emerging biotechnology area.

Senator MATHIAS. So, what you are saying as I hear you is that this is not merely a question of equities between individuals, but that there is an unevenness in the national treatment of this subject matter.

Mr. MOSSINGHOFF. That is exactly right, Mr. Chairman.

Senator MATHIAS. And that such discrepancy in national treatment results in substantial economic impact in the case of the United States.

Mr. MOSSINGHOFF. That is right. And I think it has an impact, also, in that the companies who make decisions today to invest in research and development have to see some effective protection out there, if they are successful in their efforts. And so the impact, even though the protection might be prospective, the impact is immediate. Of course, Dr. Ostro certainly is the expert there and may want to add to that.

Senator MATHIAS. I think we have to take a somewhat practical view of this subject. How would the patent holders determine that a process patent to which they made a claim was in fact being infringed? If you have a product which is imported from another country and which you find in the marketplace—Senator Leahy goes to his corner drugstore and finds it there—and you find it competing with products that you yourself have made, how would you ascertain that the imported product was made in a foreign country by that process?

How much certainty would you have when you served notice to the importer or the retailer of the foreign product, or the user or the purchaser who is about to make use of it, that in fact it is your process patent that has been violated?

Mr. MOSSINGHOFF. Mr. Chairman, I think in our industry you could find that by the very clear case. For example, Genentech just received Food and Drug Administration approval for a growth hormone, and to my knowledge the only way that can be made artificially is through the process of Genentech. And so if that hormone were to be placed on the market, clearly there would be an inference, presumption, conclusion, virtually, that that would be made by a process that was invented by Genentech, as an example.

It would seem to me that the other boundary might be products that could be made by any number of processes, and there may be—I am sure this is so among the member companies of PMA—a simple request from one business executive to another asking "Are you using my product, or using my process to make it?" and a good-faith answer would take care of the situation.

Senator MATHIAS. I can see in the biotechnology field that that might be true, because you are dealing with a very new and really a pioneer industry, so that it might be easier to draw this inference or to lead from an inference to an implication, if not to an assumption.

But Mr. Massengill mentioned amorphous metal. I am told that this is amorphous metal.

Mr. MASSENGILL. That is correct.

Senator MATHIAS. It does not look and feel much different from the foil that my wife uses for many household purposes. I assume, however, that this has extraordinary qualities.

Mr. MASSENGILL. You can be sure it is very different from aluminum foil.

Senator MATHIAS. But how do you create the inference which Mr. Mossinghoff referred to when you are dealing with amorphous metal?

Mr. MASSENGILL. Well, in our many years of development of this product, we have of course experimented with many different types of processes. And we have discovered that the only commercially viable way that we know that the product can be made is on a single roll from a melt-cast or by some other means of depositing the material on a single roll. That gives it a different surface texture. If you will notice, it has one side that is bright and shiny, and the other side is dull.

Senator MATHIAS. Just like the household foil that we use.

Mr. MASSENGILL. Well, they do not make aluminum foil by the same process, but foil does have different surfaces. But if you make material on a single roll, under containment, and the material has an amorphous structure, we can draw an inference that it is made by our process.

Senator MATHIAS. And is that inference strong enough that you would not feel foolish going into court to try to protect your process if you had the ability under this legislation to do so?

Mr. MASSENGILL. Not at all. In fact, we went into court into the ITC, and the administrative law judge held that 11 companies were violating that process.

Senator MATHIAS. So there is a practical value to this legislation, in your view; it is not simply a theoretical right, but is one that can be enforced.

Mr. MASSENGILL. There will be certain products wherein it will be very difficult to identify a particular process by which they are made. But I think on balance, a diligent effort can be made, and those numbers of products can be narrowed to a very few.

Senator MATHIAS. All right. But you say you have been through the remedies provided by the ITC. Would it be adequate to simply beef up the Trade Act a little bit and stick with those ITC remedies? Why not do that, rather than to add process patents to the patent statutes?

Mr. MASSENGILL. I think we need both. We certainly need the patent laws amended to put us on an equal basis with our trading partners. We have heard a lot of testimony on that subject this morning, and I will not go into those details.

I think we need to amend section 337 of the Trade Act. It serves a very useful role. It is primarily a trade bill, as we know. But when patents are involved, we feel that it should be amended along the lines of the bill that was just introduced by your colleagues, Senator Lautenberg and Senator Roth.

But 337, even as amended by their proposal, would not be a complete remedy. There are many reasons why it is not a complete remedy. No attorneys' fees can be awarded for willful infringement that is found; no damages for past infringement. An infringer can continue to infringe during pending litigation. There is no disincentive against continuing to infringe. They can enjoy the profits while the proceeding is ongoing. It is sort of like pirating out of some of the Southeastern countries; they just change their product or move their operations, and there are no damages assessed against them. It is not like a patent law remedy where a contempt of court sanction may be hanging over their head.

Senator MATHIAS. Now, you say that that is the case with the ITC proceeding. But one concern the Congress has got to have is whether this bill reverses that too radically, that it would encourage the harassment of the small importer, make it too easy to litigate every one of these suspicions and lead to frivolous litigation that could seriously prejudice importers.

How about that?

Mr. MASSENGILL. Well, I have to agree that we are a very litigious society. But experience has already shown that that will not be the case. The circumstances already exist where there could be wholesale litigation if patent owners wanted to bring such litigation with regard to product patents or products made by patented processes performed in this country. I have not seen that occurring. I do not see why there would be any difference in litigation concerning products that are made abroad. I think that is just a hollow call by someone; it's nonsense.

Senator MATHIAS. Any other comments on that? [Pause.]

No disagreement.

Let me say to you what I said to the previous panel, that other members who are not able to be here may well have questions, so if you are agreeable, we will keep this record open for a reasonable time to submit written questions, and your responses will be included as part of your testimony.

Thank you very much. Again, I am sorry you were delayed by that vote, but that is beyond the ability of the Chair to control.

Thank you.

Our next witnesses are Mr. William F. Haddad, chairman of the Generic Pharmaceutical Industry Association; Alfred B. Engelberg, patent counsel for the Generic Pharmaceutical Association; and Nancy L. Buc, counsel for the National Association of Chain Drug Stores.

As the veteran of this panel, we will ask Mr. Haddad to lead off.

STATEMENT OF A PANEL, CONSISTING OF WILLIAM F. HADDAD, CHAIRMAN, GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, NEW YORK, NY; ALFRED B. ENGELBERG, ESQ., PATENT COUNSEL, GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, NEW YORK, NY; AND NANCY L. BUC, ESQ., COUNSEL, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, ALEXANDRIA, VA

Mr. HADDAD. Thank you very much, Senator. Last time, we talked about dirt farming. I nearly sent you some potatoes and leeks, but I could not figure how to get them to you.

Senator MATHIAS. Well, we would probably have to turn them over to the Ethics Committee, anyway—unless they were within the time-honored traditional rule of the Senate that they were "neither heavier than an old ham nor wetter than a cork."

Mr. HADDAD. My name is William F. Haddad. I am the chairman of the GPIA, and chief executive officer of Danbury Pharmacal, a generic drug company.

GPIA members manufacture and distribute approximately 80 percent of the generic drugs produced in this country. There is some confusion about what a generic drug is, but Mr. Mossinghoff was correct in saying that the PMA companies last year distributed 80 percent of the generic drugs. We frequently make those drugs for the large companies, and they, in turn, sell them at about two to four times our prices.

The 80-percent figure, thanks to your legislation last year, is probably about 70, headed toward 50. So as a result of the Drug Price Competition Act, there has been a dramatic increase in the percentage of true generics, the lower cost generics.

At the outset, let me say one thing. We reaffirm our support for patent protection. We demonstrated that last year when we signed off on the Drug Price Competition and Patent Restoration Act of 1984. But I am troubled, and I am strongly opposed to the use of the patriotic idiom to reduce competition. We prefer to engage in the free marketplace of ideas and products, but to wave the American flag in critical times like this to cover other objectives does not sit too well with me, as you will see from my testimony.

Senator MATHIAS. You are a disciple of Dr. Samuel Johnson.

Mr. HADDAD. Not quite.

Senator MATHIAS. Do you remember Dr. Johnson?

Mr. HADDAD. You will have to refresh my memory.

Senator MATHIAS. He said that "Patriotism is the last refuge of the scoundrel."

Mr. HADDAD. I just used that in the paraphrase for a pharmaceutical article, but I did not know the source.

Senator MATHIAS. Well, I am glad to have been able to supply the source for you. I must say that there was someone else whose name I do not remember who said that in making that comment, Dr. Johnson had overlooked the unlimited potential of reform.

Mr. HADDAD. I said that the last refuge of the pharmaceutical companies is to plead research.

I believe the members of this subcommittee are familiar with George Orwell's "1984" in which war is peace, freedom is slavery, and ignorance is strength. That was all part of a new language

called "Newspeak," based on a theory called "Doublethink." Doublethink, as you recall, was the ability to take two mutually exclusive concepts and advocate both simultaneously with the intensity and moral conviction of a religion.

When I hear the statements of some witnesses on process patents, I am reminded of Doublethink. They are all for drug price competition and patent restoration passed by the Congress last year. And now they are all for this legislation. Those two positions are mutually exclusive.

What this legislation can do is negate the Drug Price Competition Act.

Some others claim the legislation will protect U.S. jobs. It does not. You will find that exactly the opposite would happen—unemployment becomes employment.

Others claim this legislation will protect U.S. business. What it does is impose a legal and financial hardship on almost every U.S. retailer from the corner drugstore to the chain store, every five-and-dime store, every supermarket is in jeopardy. Hardest hit, as usual, are the small businessmen who do not maintain house counsel.

Let me get to the facts. The nature of the generic business is such that we obtain our raw materials overseas, 90 percent or more. We would love to obtain those raw materials in the United States, but nobody will sell them to us here.

Under the so-called liberalized provisions of this proposed legislation, we would be found guilty de facto before trial under the process patent section.

The practical circumstance of implemention is such that we fear, with some foundation, that the legislation will cut off our supply of raw material. Using "Doublethink," last year's victory becomes this year's defeat.

The proposed new process legisla n would make generic dosage from manufacturers liable for all d acts of process patent infringement committed by their f ign suppliers and would in effect shift the burden of proving or disproving the actual existence of infringement to them. And that is the heart of our complaint.

Worse yet, it places a substantial financial damage liability on generic manufacturers which will have a chilling effect on the ability of generic drug manufacturers to do business.

The holder of a process patent, by simply asserting that there may be patent infringement—without even knowing if, in fact, that is the case—can create a potential financial risk for the generic manufacturer which makes it impossible for that manufacturer to do business on a rational basis.

Only a very, very small amount of active ingredient usually goes into a bottle of tablets or capsules. Therefore, the amounts of bulk material which the generic industry imports are relatively small, and the dollar volume of that business is not great.

Thus, the foreign suppliers often lack incentive to defend claims, particularly frivolous claims, of infringement. The processes used by the suppliers often embody valuable trade secrets, which gives them a competitive edge in the international marketplace. They are often unwilling to disclose those secrets, even under court-ordered secrecy, because the risk of inadvertent disclosure far out-

weighs the minimal value that business may lose in particular, which they may lose for these products.

Those who claim that there is no legitimate reason to fear the inadvertent disclosure of trade secrets need only look at Coca-Cola's current refusal to disclose the formation for its product to the court, in secret.

Those who would argue that the foregoing problem can be avoided merely by making sure that suppliers avoid infringement do not understand the complex workings of the patent system. And I must say I was surprised to see the Patent Commissioner give you an interpretation of the history of the process patents which is not accurate; I hope he will correct the record when you send it to him.

Each of the pharmaceutical companies own thousands of patents. They do not list the identity of the particular patents which are relevant to a particular product in some crucial place. It would cost tens of thousands of dollars to conduct the patent studies needed to determine the presence of absence of infringement, assuming the information in the processes used abroad was available to the generic manufacturer.

There is a much simpler way. The patent holders should enforce their large foreign patent portfolios directly against the foreign manufacturers rather than bring coercive lawsuits against innocent purchasers. And as you know, the history of the law on patents is in that direction.

At the time of the negotiations leading to the 1984 Act, generic manufacturers were well aware of the fact that actions for infringement of process patents by acts abroad could be the subject of proceedings in the ITC. Indeed, at the very time a process patent action by Merck relating to Indomethacin was pending. We were not asking for repeal of the ITC procedure, which seemed to work for the last witness; nor are we looking for a free ride in cases of proven process patent infringement. However, the ITC procedure serves as a filter for frivolous charges of infringement.

I think the other witnesses will detail that for you.

Even the Patent Term Restoration portion of the 1984 Drug Act recognized that process patents should not play a significant role in the competition between brand name and generic drugs. The original drafts of title II, which covers Patent Term Restoration, essentially excluded the possibility of extending any process patents except in the limited and unlikely circumstance that there were no relevant product or therapeutic use patents, which covers the biotech area that you heard about.

Senator MATHIAS. Mr. Haddad, because I interrupted you, I have let you go through the red light——

Mr. HADDAD. With all due respect, Mr. Chairman, the Government had 1½ hours to argue their case.

Senator MATHIAS. That is right, and that is why I want to give you, if not equal time, adequate time. But we also have another vote on the floor, which is a problem.

Mr. HADDAD. All right. Let me just skip through this. I will submit this for the record—let me do that—and then I will respond to your questions.

My basic argument, Senator, is if it ain't broke, don't fix it. ITC is working. There is not a case that anybody can point to where the

ITC has not protected process patents. The burden put on us by this procedure, in effect, could dry up our raw materials. If they in turn will sign an agreement to sell us material here, we would buy it, but that is not happening in the marketplace.

So the realities of the marketplace are such that this legislation would wipe out what you did last year. And the penetrations that I mentioned which help a consumer are real; they would be reversed. They would achieve by this back door what they could not achieve in the front door.

And we also put in jeopardy, as Senator Leahy pointed out, every small drugstore with all the OTC items. I do not know how you are going to get around that.

The way we sue in this country, we get sued, everybody gets sued; they sue everybody from the doctor to the manufacturer to the drugstore. They have these class actions, and they catch everybody. So I mean, they are not going to make an exception here.

Senator MATHIAS. Well, I will not ask you this now, but think about it. The question is whether it should be prospective or retrospective.

Mr. HADDAD. Well, the answer is easy—it should not be at all.

[Mr. Haddad's prepared statement follows:]

Prepared Statement of William F. Haddad

My name is William F. Haddad. I am the Chairman of the Generic Pharmaceutical Industry Association and the Chief Executive Officer of Danbury Pharmacal, a generic drug company. GPIA members represent approximately 85 percent of the generic drugs produced in this country.

I believe the Members of this Subcommittee are familiar with George Orwell's 1984, in which which war is peace, freedom is slavery and ignorance is strength. That was all part of a new language, Newspeak, based on a theory called Doublethink. Doublethink, as you recall, was the ability to take two mutually exculsive concepts and advocate both simultaneously with the intensity and moral conviction of a religion. When I hear the statements of some of the witnesses on process patents, I am reminded of Doublethink. They are all for the Drug Price Competition and Patent Restoration Act passed by the Congress last year, although, if you look closely, that may not be true. And, now, they are all for this legislation. Those two positions are mutually exclusive. What this legislation can do is negate the Drug Price Competition Act, but in the spirit of Doublethink, I doubt that this troubles them. In the pharmaceutical industry, for three decades, and continuing into the present, for some companies, Doublethink is a marketing philosophy turned into a religion.

Here are the facts. Some 90 percent of the raw materials which we use to make generics in this country are imported. That's the nature of this business. If we could obtain the raw materials here, we would buy them here. But for a confluence of circumstances that is not possible. Under the so-called "liberalized" provisions of this proposed legislation, we would be found guilty de facto, before the trial. The practical circumstance of implementation are such that we fear,

with some foundation, that the legislation will cut off our supply of raw material and last year's legislation would be reduced to the concept that Doublethink victory is defeat. Let me explain.

The proposed new process legislation would make generic dosage form manufacturers liable for alleged acts of process patent infringement committed by their foreign suppliers and would, in effect, shift the burden of proving or disproving the actual existence of infringement to them. Thus, it creates essentially the same problem that certification of process patents would have created under the 1984 Act. Worse yet, it places a substantial financial damage liability on generic manufacturers which will have a chilling effect on the ability of generic drug manufacturers to do business. The holder of a process patent, by simply asserting that there may be patent infringement (without even knowing if, in fact, that is the case) can create a potential financial risk for the generic manufacturer which makes it impossible for that manufacturer to do business on a rational basis. Only a small amount of active ingredient usually goes into any tablet or capsule. Therefore, the amounts of bulk materials which the generic industry imports are relatively small, and the dollar volume of the business in any product is not large. Thus, the foreign suppliers often lack incentive to defend a claim of infringement. The processes used by the suppliers often embody valuable trade secrets which give them a competitive edge in the international marketplace. They are often unwilling to disclose those secrets, even under court ordered secrecy because the risk of inadvertent disclosure far outweighs the minimal value of the business which they may lose on a particular product. Those who claim that there is no legitimate reason to fear the inadvertent disclosure of trade secrets need only look at Coca-Cola's current refusal to disclose the formulation for its product to the court, in secret, in Coke's pending litigation with bottlers.

Those who would argue that the foregoing problem can be avoided merely by making sure that suppliers avoid infringement do not understand the complex workings of the patent system. Each of the pharmaceutical companies owns thousands of patents. They do not list the identity of the particular patents which are relevant to a particular product in some central place. It would cost tens of thousands of dollars to conduct the patent studies needed to determine the presence or absence of infringement, assuming the information in the processes used abroad was available to the generic manufactuer. There is a much simpler way--the patent holders should enforce their large foreign patent portfolios directly against the foreign manufacturers rather than bring coercive lawsuits against innocent purchasers.

At the time of the negotiations leading to the 1984 Drug Act, generic manufacturers were well aware of the fact that actions for infringement of process patents by acts abroad could be the subject of proceedings in the ITC. Indeed, a process patent action by Merck relating to Indomethacin was pending at the time the negotiations leading to the 1984 Act were in progress. We are not asking for repeal of the ITC procedure. Nor are we looking for a free ride in cases of proven process patent infringement. However, the ITC procedure serves as a filter for frivolous charges of infringement. Innocent purchasers of foreign made goods, who have no knowledge of how those products were made, are not faced with the coercive effect of enormous damage claims. Rather, the ITC expeditiously determines if infringement exists and, if so, prevents, the further importation of goods. Since, by law, ITC proceedings must be over within a year, the damages suffered by a patent owner are minimized by a rather short period of infringement--if, indeed, there is infringement. In contrast, last year the PMA companies insisted that it took at least 30 months to resolve a patent controversy in the courts and ultimately prevailed on Congress to provide them with an automatic 30 month injunction as part of the patent certification process.

Even the Patent Term Restoration portion of the 1984 Drug Act recognized that process patents should not play a significant role in the competition between brand name and generic drugs. The original drafts of Title II, which covers Patent Term Restoration, essentially excluded the possibility of extending any process patents except in the limited and unlikely circumstance that there were no relevant product or therapeutic use patents. Ultimately, in order to simplify administration of the Patent Term Restoration system, the holder of the approved NDA was given the ability to select either a product, process or therapeutic use patent for extension. However, extensions are only available in those circumstances where a new chemical entity is receiving FDA approval for the first time. Obviously, in the overwhelming number of circumstances, the patent to be extended will be a product patent or a therapeutic use patent. Indeed, none of the more than two dozen applications for patent extension which have been filed during the past year seek to extend the life of a process patent.

Patents which cover manufacturing processes were deliberately omitted from the patent certification process of the 1984 Act for at least two reasons. First, it was recognized that there are almost always several different methods for manufacturing a particular product and that product and therapeutic use patents are the dominant means for protecting pharmaceutical inventions.

Second, and most importantly, it was recognized that U.S. generic drug manufacturers do not usually engage in the manufacture of the active drug ingredient but, rather, purchase those ingredients from third parties. In most cases, the third party is located abroad. The processes used by those third parties constitute valuable trade secrets and are never disclosed to the generic dosage form manufacturers. Process patents were therefore eliminated from the patent certification scheme because it was recognized that expanded enforcement of process patents would

permanently prevent generic competition. A generic manufacturer would be in no position to certify non-infringement without actual knowledge of the manufacturing process. Since it does not have the knowledge needed to make the certification, it could never obtain an ANDA approval so long as any process patent was listed.

It seems obvious from the foregoing that pharmaceutical companies will seek to enforce process patents against generic manufacturers only after the extended product and use patent protection provided by the 1984 Act have expired. At least one process for the manufacture of the drug product will be disclosed in the expired patent. Whether that process is the most efficient process or not is truly irrelevant to competition between generic and brand name drugs because the small amount of active ingredient used in each tablet is not as significant a factor as the vast price difference between generic and brand name drug products. Indeed, in most cases, the bottles, labels and caps far exceed the cost of the tablets. Nevertheless, process patents can be used to impede the competition contemplated and desired by the 1984 Act by forcing generic makers to change suppliers or processes after an ANDA has been approved, thereby forcing them off the market until they rerun the guantlet of the regulatory review process.

In the final analysis, Congress enacted the 1984 Drug Price Competiton Act at the request of the major drug dompanies in order to maximize protection for new products and new therapeutic uses and create the incentive for new inventions. That Act created special patent provisions for prescription drugs. It may be that additional patent protection is needed in other industries, but pharmeceutical patents should be exempted in view of the '84 Act.

And we also live within the legal boundaries of the ITC which offers many of the protections of this legislation but

without the non-judicial zingers. It is not that we are pleased with the ITC process, but it is in place, we acceed to it, present our case on demand, and follow the resulting stipulations if and when they are decided. Now, if the major pharmaceutical companies are worried about infringement of process patents, they take their case to the ITC. In that vein, where it is the ITC failure to act which makes this legislation necessary? No one could point to a a case last year and none can point to a relevant case this year. As we conservatively advocated with patent restoration for the last four years, "if it ain't broken, don't fix it."

Senator MATHIAS. Mr. Engelberg.

STATEMENT OF ALFRED B. ENGELBERG

Mr. ENGELBERG. Thank you, Senator.

My name is Alfred Engelberg, and I am counsel to GPIA.

I would like to just submit my statement and spend some time trying to respond to some of the things that have been said this morning.

First, on the question of loophole and consistency and the issue of whether or not process patents were unfairly treated, I think a very important point has been missed. The U.S. patent law defines as an infringement "the making, using, or selling of a patented invention in the United States."

The reason for the "United States" limitation is very simple—we cannot extend our laws overseas——

Senator MATHIAS. We try, sometimes.

Mr. ENGELBERG. The same "make, use, or sell" doctrine applies to products and applies to processes, but the people who are caught on the question of liability are quite different. If the patented invention is a product, the manufacturer is liable, because he makes; the distributor is liable because he sells, and the ultimate consumer is liable because he uses. If the patented invention is a process, there is no possible making or selling—there is the only possibility of use of the process.

The system works very well, or worked very well for most of its history, because it inherently only makes those people liable that have an ability to defend themselves. Someone asked a question about what a retailer does in the case of a product patent infringement. The answer is very simple. For a dollar—or, I think now it is a dollar and a half, with the new patent fees—you buy a copy of the patent, you call a patent attorney, and while you may not be able to get into the esoteric questions of whether or not the patent is valid without spending a lot of money, in the vast majority of cases you can compare the patent claims to the product and know if there is a palpable case of infringement.

One other point, because it has come so many times, about the historical development and us being out of step with our trading partners. No one mentioned here this morning that most of the so-called developed countries such as Germany, Japan, and some of the other countries that were mentioned, until 15 or 20 years ago, provided no product protection whatsoever in the case of chemicals. They had a process law similar to the one we are talking about here this morning, because without that process law, there would have been no protection at all for brand new product inventions.

The philosophy underlying why they went the way they did, and why we went the way we did, is a very long discussion, but the fact is that U.S. patent law has been and remains stronger than its foreign counterparts.

Now, a time arose in the history of patent law——

Senator MATHIAS. Because of the product protection.

Mr. ENGELBERG. Because we had product protection and they did not.

A time arose in the history of the patent law where we recognized that because of foreign imports there could be a problem in some product and processes cases. We did not then turn to suing innocent customers. What we did was create a trade law within the ITC that acts as a filter.

Again, no one has mentioned—and I think it has a lot to do with why we are here today—that the ITC maintains an investigative staff. That staff acts as a filter for frivolous claims, for bad-faith claims, and for mistaken claims of infringements, and it assures that there is a forum where cases can be heard and where patent owners can be protected without putting a gun to the head of an innocent retailer.

One of the major problems with this bill—and I think you will hear it in subsequent testimony—is that you have a decision to make when you buy a product. And as the Supreme Court said 100 years ago, no one wants to buy a product if they have to buy a lawsuit with it.

The second reason, other than the leverage that this legislation would provide to the proponents of being able to make claims that are not defendable, is that the ITC has a domestic industry requirement. Witness after witness here this morning has said the ITC is wonderful, let's not get rid of it. You get speedy justice, and in fact, you can get temporary exclusion orders in 5 months and the case is over in a year. It is a procedure which minimizes damages. Why do they want to run away from it?

The answer is that the only way you can protect the process patent today is in the ITC, and to do that, you must prove that there is a domestic industry operating under the patent. Simply put, because it is a fairly easy standard in the ITC, you have to prove that somebody is working the patent in this country, someone is actually using the patent in this country.

The proponents of this legislation do not want to prove that. They want to be able to go offshore, just like everybody else, when it is cheaper and it is in their interest. And what they are ignoring, and what again has failed to be mentioned here this morning is that 42 percent of all patents are now being issued to foreign corporations and foreign individual inventors. In fact, IPO published a

list that appeared in the B&A Journal last week that says that 7 out of the 11 top patent—getters in 1984 were foreign companies like Hitachi and Toshiba; that the top companies on the list were multinational worldwide companies like IBM and General Electric.

This bill in its present form will not create jobs. It may well be that patents can be an instrument of national trade policy, but not by eliminating a domestic industry requirement which now exists.

Thank you.

Senator MATHIAS. Thank you very much.

[Mr. Engelberg's submissions for the record follow:]

Prepared Statement of Alfred B. Engelberg

My name is Alfred Engelberg, and I am Patent Counsel to the Generic Pharmaceutical Industry Association. I have been engaged in the practice of patent law for over twenty years and during that period, have been a Patent Examiner in the United States Patent and Trademark Office, a patent attorney for a large multi-national corporation, a patent trial attorney for the United States Department of Justice, and a private practitioner.

The proponents of this legislation urge that, under current law, patents claiming manufacturing processes are unfairly treated in a manner which is inferior to the treatment accorded to product patents; that the protection afforded to process patents by the International Trade Commission is inadequate; that the failure to extend the protection of process patents in the U.S. is out of step with the patent law of other countries; and that the proposed legislation will protect or create jobs. None of these arguments can withstand any serious scrutiny. In fact, the present system of protecting and enforcing process patents works just fine! When all of the facts are considered, it is apparent that proponents of this legislation have only two real, but unsupportable, purposes, namely:

(1) To create the ability to enforce a process patent in the United States even though the patent owner is not engaged in any domestic industry under the patent and is, itself, practicing the process abroad.

(2) To expand the use of threats of process patent infringement and the possibility of substantial attendant monetary damages against the innocent purchasers and distributors of imported products as an unfair means of capturing all or a substantial portion of that business by the patent owner irrespective of the merits of the patent infringement claim.

THE PROPOSED LEGISLATION WILL NOT CREATE JOBS; IT MAY EXPORT JOBS

Under current law, the only way in which it is possible to obtain extraterritorial enforcement of patents covering manufacturing processes is an action before the International Trade Commission under 19 U.S.C. §1337(a). The ITC will bar the importation of goods made abroad by a U.S. process but only if the patent owner or its U.S. licensees are actually practicing the patented invention in the U.S. If the patent is not being "worked" in this country, then there is no injury to U.S. economic interests or jobs.

The proponents of this legislation seek the elimination of the "domestic industry" requirement which is present in ITC proceedings by creating a new proceeding in the District Courts. Specifically, they wish to be able to enjoy full enforcement of process patents under circumstances where the patent owner is not using the patented process in the United States. But the elimination of the "domestic industry" requirement also eliminates the basic premise which has been relied upon to attract Congressional support for this legislation, namely, that this bill will result in new jobs. In fact, this bill could result in the net export of jobs.

Simply put, the "domestic industry" requirement in current ITC law provides a substantial incentive for establishing U.S. manufacturing facilities for the practice of a patented process because that is the only way in which the patent owner can obtain the enforcement of the process patent against foreign manufacturers. This incentive will disappear if the proposed legislation is enacted. Patent owners will be free to move their domestic manufacturing operations abroad without losing any domestic patent enforcement rights.

The potential impact of the "domestic industry" requirement is not theoretical. Statistics recently published by the Intellectual Property Owners Inc. indicate that the number of United States patents being issued to foreign individuals and corporations has been continuously rising and accounted for 42% of all U.S. patents issued in 1984. Overall, General Electric Co. and IBM, two multi-national corporations with worldwide manufacturing facilities obtained the most U.S. patents during 1984. Close behind were Hitachi and Toshiba. Foreign firms, in general, captured 7 of the top 11 spots on the "most patents" list. Clearly, the elimination of the "domestic industry" requirement will not give these foreign corporations any incentive to build factories in the United States.

Many of the proponents of this legislation have argued that U.S. Patent Law is out of step with the rest of the world in refusing to enforce process patents more broadly. This is not the case. In fact, until recently, many of the countries which provided extraterritorial protection for process patents, provided no protection at all for new compositions of matter such as drugs and agricultural chemicals. Further, the patent laws of most countries, such as England, Germany, Holland, Japan and the rest of the industrialized world, require that a patent be "worked" by actual use of the patented invention in that country. Compulsory licensing may be ordered if a patent is not "worked." Indeed, in England, for example, compulsory licensing may be ordered even in those instances where the patent is being "worked" but production is insufficient to make products available at reasonable prices. There are also other public interest situations where compulsory

licensing may be invoked--patents covering drugs is one such area. In the final analysis, these economic overrides on the operation of foreign patent systems are comparable to the "domestic industry" requirement in ITC proceedings.

The expansion of the definition of process patent infringement is also clearly inequitable given other provisions of U.S. patent law relating to activities in foreign countries. For example, under 35 U.S.C. §104, a foreign applicant may not rely on any activities in a foreign country for the purpose of establishing priority of invention. Similarly, under 35 U.S.C. §102(a) and (b), the secret prior commercial use of a process in this country will invalidate a subsequent process patent but even a public commercial use of an invention in a foreign country cannot be relied upon as prior art for the purpose of establishing patent invalidity unless it has been described in a printed publication. These statutory provisions have their roots in the long held belief that the development and verification of evidence relating to foreign activities is too difficult and such evidence is inherently unreliable. Logic would appear to dictate that precisely the same evidentiary barriers exist with respect to proving infringement. Yet, the proposed legislation would place that burden on the innocent customer who has the least capability of dealing with the problem. In any event, if the expanded process infringement legislation is enacted without changing other parts of the patent law, it would be possible to find a foreign manufacturer guilty of infringement even though that manufacturer had been engaged in the actual commercial use of the patented subject matter for many years prior to the issuance of the U.S. patent. The inequity in such a result is self-evident. Moreover, that inconsistency demonstrates the difficulty in attempting to make important substantive modifications to the patent law on a piecemeal basis or on the basis of alleged parity with the patent laws of other countries. In that regard, it should be noted that many of the countries which enforce process patents where production occurs in a foreign country also permit reliance on prior public use or sale in a foreign country to establish patent invalidity.

THE CURRENT ITC PROCEDURE IS FAIRER AND FASTER THAN THE PROPOSED NEW INFRINGEMENT PROCEEDING

Under 19 U.S.C. §§1337 and 1337(a), the International Trade Commission (ITC) is authorized to prevent the importation of a product manufactured abroad by means of a process covered by a U.S. process patent. The following statutory provisions govern proceedings before the ITC:

> 19 U.S.C. 1337
>
> "Unfair methods of competition and unfair acts in the importation of articles into the United States,

> or in their sale by the owner, importer, consignee or agent of either, the affect or tendency of which is to destroy or substantially injure an industry efficiently and economically operated, in the United States, or to prevent the establishment of such an industry...are declared unlawful.
>
> 19 U.S.C. 1337(a)
> The importation for use, sale or exchange of a product made, produced, processed or mined under or by means of a process covered by the claims of any unexpired valid United States Letters Patent, shall have the same status for the purpose of Section 1337 of this Title as the importation of any product or article covered by the claims of any unexpired valid United States Letters Patent."

It has long been established law that the importation of a product covered by a valid, unexpired U.S. product patent is an act of unfair competition under 19 U.S.C. §1337.

The practices and procedures of the ITC in enforcing patent infringement claims is generally recognized by the patent bar as a remedy for patent infringement which is substantially superior to conventional actions for patent infringement in the District Courts. This superiority stems from several factors including:

(1) The ITC is required by law to render a final decision on a patent infringement claim under Section 337 within one year from the time the claim is first made. There is no time limit for patent infringement actions in the District Courts and the typical case usually lasts for several years before a judgment is entered. Indeed, last year the major drug manufacturers insisted that a minimum of 30 months was required to litigate drug patent controversies in the District Courts. For that reason, the Drug Price Competition and Patent Term Restoration Act of 1984 provides a 30 month delay in the FDA marketing approval for a generic drug if there is a patent controversy.

(2) A Section 337 action in the ITC is a suit against the goods and not against a particular party. For

that reason, all parties who deal in the goods in the domestic market are usually notified and, in any event, are affected by the ITC's decision. The usual personal jurisdiction and venue problems which arise in District Courts when multiple parties are involved are avoided. For example, a patent infringement suit against a New York importer, which resulted in an injunction against further infringement, would not bar a California corporation from continuing to import the same product or a similar product from the same or another foreign source. In contrast, a Section 337 proceeding in the ITC is a proceeding against all goods of the same description irrespective of the identity or location of the foreign manufacturer or domestic user of the product. If infringement is found to exist, all goods of that description will be excluded from further importation.

(3) The ITC has a regular procedure for considering Temporary Exclusion Orders. A Temporary Exclusion Order (TEO) is comparable to a preliminary injunction in a District Court action. However, preliminary injunctions are rarely granted in patent infringement actions in District Court. In contrast, under ITC Rules, a decision on a motion for TEO must be decided within five months from the time the initial ITC investigation is commenced and such orders are granted in some cases.

(4) During an appeal from an Exclusion Order or TEO, the ITC normally requires the posting of a bond equal to 100% of the value of the goods. Bonds of this size completely discourage continued importation while the appeal is pending.

(5) The interpretation of patents with respect to issues of validity, infringement and enforceability is the same in the ITC as in the District Courts. Indeed, appeals from ITC decisions in patent-based Section 337 cases are heard by the Court of Appeals for the Federal Circuit which is the same Court which hears appeals from all patent infringement cases tried in the District Courts throughout the country.

For all of the foregoing reasons, patent owners are flocking to the ITC in record numbers. In fact, in a significant number of all ITC patent cases, the patent owner had a clear choice between bringing an ITC action or commencing a suit for patent infringement in a District Court. Indeed, although a great deal of attention has been focused on the ITC cases involving

Allied Corporation (In the Matter of Certain Amorphous Alloys and Amorphous Metal Articles) and Corning Glass Works (In the Matter of Certain Optical Waveguide Fibers) as demonstrating the inadequacy of the ITC remedy and the need for this legislation, it is generally overlooked that Allied and Corning voluntarily chose that forum rather than the District Court and that Allied won its case. In fact, Corning chose both forums and, although it lost in the ITC because it could not prove any injury, it still has a pending case involving infringement of the same U.S. patent by the same Japanese company, in the United States District Court for the Southern District of New York (Civil Action 84-CIV-1955 WCC). Thus, in considering the need for this new legislation, one must be careful to distinguish between situations where a particular party is disappointed with the result in a particular case and those situations which actually require new legislation. Otherwise, Congress runs the risk of becoming the court of last resort for every disappointed litigant.

It is true that the patent owner in an ITC proceeding must satisfy certain statutory requirements in addition to patent ownership, validity and infringement. Specifically, the patent owner must establish that it is engaged in a domestic industry; that the domestic industry is efficiently and economically operated; and that the importation of the goods has the effect or tendency to destroy or substantially injure an industry or prevent its establishment. These requirements are not substantial barriers to patent enforcement by the ITC. For example, in the Allied (Amorphous Metals) case, the ITC found that a domestic industry existed because products were available for sale, the company was marketing the product, and the company had management and financial capabilities. These findings were made even though Allied's business was in its infancy, the evidence demonstrated that the prices for the products were too high, and that Allied was losing money on the venture. Moreover, the ITC found that Allied met the "injury" test, even though the infringers had only provided a few samples of their products to potential customers so that the products could be qualified for future sales to those customers.

The ITC procedure is particularly effective in cases involving process patents because the Commission maintains an Office of Unfair Import Investigations consisting of qualified attorneys representing the public interest whose mission is to investigate the allegations made by the patent owner to determine whether or not a substantial basis exists for the §337 claim of patent infringement. The role of OUII is particularly crucial in process patent investigations because the investigative staff can and does look behind the self-serving allegations of infringement set forth in a Complaint and assists the Commission in determining whether a substantial basis exists for a charge of infringement

in those circumstances where the importers have no information with which to defend against the infringement allegation. Moreover, because an adverse decision by the ITC will affect the foreign manufacturer's entire business in the product in the United States rather than its business with a single customer, as would be the case in a typical District Court proceeding, the potential for a general Exclusion Order provides a greater incentive for cooperation from the foreign manufacturer in producing evidence to establish the presence or absence of infringement. In any event, the Administrative Law Judges of the ITC can and do draw adverse inferences on the ultimate question of infringement if a foreign manufacturer refuses to cooperate in discovery proceedings. See, In Re Multi-Cellular Plastic Film, USITC Pub. No. 987 at 7 (June, 1979).

CURRENT PATENT LAW DOES NOT DISCRIMINATE AGAINST PROCESS INVENTIONS; THE NEW PROCEEDING WOULD CREATE LIABILITY WITHOUT FAULT

Current patent law provides that (35 U.S.C. §271(a):

> "Whoever without authority, makes, uses or sells any patented invention, within the United States during the term of the patent therefor infringes the patent."

The "patented invention" may be a machine, an article of manufacture, a manufacturing process or a composition of matter. The law with respect to infringement does not change with the nature of the invention. Manufacturing process patents are subject to precisely the same law as product patents. But the identity of the parties who are actually liable for patent infringement varies as a result of the inherent differences between a product and a process for manufacturing the product. Thus, for example, if the patented invention is a new chemical which is useful as a drug or pesticide, the manufacturer of that compound is liable for infringement because he both "makes and "sells" the compound. The wholesalers and retailers of that compound are also infringers because they "sell" the compound. Even consumers are liable for infringement because they "use" the patented invention.

Suppose the compound in question is ordinary table salt and someone discovers a new process for extracting it from the ocean. It is certainly possible to obtain a patent on this new manufacturing process if it is new. But the salt itself is old and is not patentable. The patent on the new process for making salt would certainly be enforceable against a competing manufacturer who "uses" the patented manufacturing process. But, the company that purchases the salt or who uses the salt is not liable for patent infringement because it did not make, use or sell the patented process invention. The product which it either sold or used was still ordinary table salt which could have come from a salt mine, from the ocean or from any one of numerous known

chemical reactions which produce salt as a by-product. These innocent purchasers neither know nor care how the salt was made. They are not liable as infringers under current law because the salt is not the patented invention and they, as distributors or consumers, did not make, use or sell the manufacturing process which was the patented invention.

The foregoing hypothetical example is not far-fetched. The vast majority of patents covering manufacturing processes do not produce new and patentable products. Rather, they are directed to new methods for producing old products. If the product itself is new, it will usually be the subject of its own patent. Thus, the current system of patent enforcement applies a consistent "make, use or sell the patented invention" standard to determine who is and who is not an infringer, irrespective of whether the patented invention is a machine, a manufacturing process or a product.

For the first time in the history of U.S. patent law, the proposed legislation would place a burden and liability for patent infringement on parties other than a party who made, used or sold the patented invention. It would make distributors, wholesalers, retailers and consumers liable for the infringement of a manufacturing process patent, even though they, themselves, never engaged in the making, using or selling of the patented invention. The buyers of ordinary table salt could be dragged into court and forced to defend a claim that the salt which they purchased was extracted from the ocean by a patented process rather than having been mined or produced by some other method. Obviously, the information needed to defend such an infringement claim is not apparent from inspection of the salt and is not in their possession. Moreover, they do not really care where the salt came from, provided that it is interchangeable with salt from other sources and is competitively priced.

The coercive effect of a lawsuit against these innocent and unknowledgeable customers is self-evident. Faced with attorneys' fees, a damage claim of unknown amount and an inability to independently determine whether, in fact, any infringement has occurred, they will usually take the only practical avenue which is open to them, namely, to purchase salt from the party making the claim of infringement irrespective of the merits of that claim. As the U.S. Supreme Court wisely stated more than 75 years ago in recognizing the coercive nature of a patent infringement claim against a customer of an infringing manufacturer:

> "No one wishes to buy anything if with it he must buy a lawsuit."
> Kessler v. Eldred 206 U.S. 1065, 1068 (1907)

The foregoing thought was echoed by the Justice Department in opposing an attempt to pass similar process patent legislation

almost twenty years ago. During 1967, Donald Turner, The Assistant Attorney General in charge of the Anti-trust Division, testified:

> "I would say that the two main questions we raised were these: (1) Has any need been shown which would make the proposal something of considerable importance? We were not aware that any extensive need had been shown, and the President's Commission report simply has the conclusory statement that there was.
>
> (2) A provision of this kind certainly in the blanket form in which it was proposed...would impose some very serious practical problems for importers of goods. If I am an importer of a goods, a product, and somebody comes to me and says this product infringes a product patent held by him, a U.S. product patent held by him, my job of determining or having it determined for me whether that is true, whereas it may be difficult, is relatively easy. You have two products. You can get a patent lawyer, and he can look at the prior art. He can attempt to establish how good the patent is and you compare the two products. There they are. Now, if I am an importer and somebody comes to me and says, "You are infringing not because the product is an infringing product, but it was made by a process which infringes my U.S. process patent," the only way I can determine or my lawyer can determine whether that is so is to make an investigation abroad in the country of origin and try to endeavor to find out whether the product that I have imported was in fact produced by an infringing process. That can be a very costly operation. (Emphasis added).

See, General Revision of the Patent Laws, 1967, Hearings on H.R. 5924, H.R. 13951 before Subcommittee No. 3 of the Committee on the Judiciary, House of Representatives, 90th Cong. 1st. Sess., 146 (1967).

Those who would argue that innocent purchasers can put pressure on their supplier by withholding purchases or demanding indemnification agreements have not given full consideration to the realities of a marketplace in which there are often many layers in the chain of distribution between the manufacturer and the ultimate purchaser, and many purchasers who lack economic leverage over their sources of supply. For those reasons, lawsuits against customers rather than infringing manufacturers are a favorite tactic of litigators in unfair competition and product patent infringement cases. The pressure which will be placed upon these innocent purchasers as a result of the time, expense and uncertainty of litigation will coerce them into changing their sources of supply, irrespective of the merits of the infringement controversy.

The industry proponents of this legislation, are primarily very large corporations and are accustomed only to situations where they have leverage over their manufacturing suppliers. In that limited setting, it may well be that the purchaser has actual knowledge of the manufacturing processes or the means to gain access to that knowledge. However, this legislation is not limited to patent infringement issues arising between large industrial companies. To the contrary, it affects every product which moves in commerce in the United States. In actual practice, the accused infringer's decision to defend patent infringement litigation may well be based on other factors such as the amount of business involved; the value of the trade secrets involved; the identify of the patentee; and the nature of the worldwide competition between the patentee and the accused infringer. Innocent buyers may well lose access to valuable sources of supply, even though there is no actual infringement, simply because a foreign manufacturer legitmately refuses to make a disclosure of trade secrets to a competitor. Those who would argue that Protective Orders can be entered by the courts to protect trade secrets need only look at Coca-Cola's recent refusal to produce the formula for Coke despite the ruling of the Delaware Federal District Court that the formula was relevant to the litigation and that it would be protected from disclosure.

The proponents of this legislation have already implicitedly recognized that the idea of bringing process patent infringement legislation against the purchasers and users of products is a bad and unfair idea. For that reason, the original version of the proposed legislation would not have created such liability in the case of products manufactured in the United States. The original bill limited suits for process patent infringement against innocent customers to imported products and required the owner of a process patent to sue the party actually alleged to be using an infringing process if the product was produced domestically. The bill, in that form, was opposed by the U.S. Trade Representative on the ground that it was unnecessarily discriminatory to foreign produced goods and would, therefore, violate this country's obligations under The General Agreement on Trade and Tariffs (GATT). That objection led to the current version of the legislation which eliminates the discrimination by authorizing customer suits irrespective of whether the products are manufactured here or abroad. In other words, an idea originally recognized as bad, namely, suits against customers, has been expanded.

The surest guarantee that patent infringement controversies will be decided on the merits, rather than by the coercive effect of litigation, is to ensure that, to the extent possible, controversies are litigated between the real parties in interest who have actual knowledge of the facts required to decide the merits of a claim. The ITC now provides such a forum.

In summary, our present law already provides for the enforcement of process patents against imported products and strikes an appropriate balance between the enforcement of patent rights and the protection of domestic industries. Unless and until a body of economic information is developed which would establish that a broader enforcement of U.S. patent rights would be beneficial to U.S. industries and U.S. jobs, there is no reason to go any further, particularly in view of the obvious flaws and unfairness in the proposed legislation.

GPIA Responses

to Written Questions of Senator Mathias

Question (1) This question seeks to expand the record on the subject of the historical origin and rationale for the different treatment under U.S. laws of process patents as compared to product patents. At the hearing, Mr. Engelberg suggested that most developed countries (including Germany and Japan) 15 to 20 years ago did not have product patent protection on pharmaceuticals and chemicals, so that process patent protection was the only available protection in these industries and it was naturally enforced more broadly with respect to imported products than our laws were.

If this is accurate, is it also true that the laws in those countries at that time held the purchasers and users as well as the manufacturers liable for products made by a process patented in that country? And if so, when these countries revised their laws to include product patent protection for pharmaceuticals and chemicals, did they also retain the stronger approach to process patent protection, or did they shift to a kind of protection analogous to the ITC remedy in our system?

Answer to Question (1)

The enclosed article by Kyoji Murayama from the AIPPI JOURNAL of December, 1984, supports Mr. Engelberg's testimony with respect to the historical development of foreign laws protecting process patent inventions. The article specifically points out the many undesirable economic and legal consequences resulting from patent systems which, unlike the American system, limited patent protection for new chemical entities to the process of manufacturing those chemicals and prohibited claims directly covering the chemicals, per se.

In a "process protection only" patent system, it would have been possible to completely escape liability for the manufacture of a new chemical entity by manufacturing in a different country. To avoid that undesirable result, infringement liability was extended to the users and sellers of products made by the patented process. However, as noted in the summary of foreign laws attached to the testimony of Commissioner Quigg (copy enclosed), most of the "process patent only" countries incorporated significant limitations in their laws (which are not present in S.1543) in order to insulate users and sellers from any meaningful liability except in those instances involving a new chemical entity. Specifically, (1) there is no presumption in favor of the process patentee unless the process covers the manufacture of a new chemical entity, and (2) infringement can only be asserted for the use and sale of the direct product of the patented process and not merely when the process may have been used as an intermediate step in the production of some other product.

Given the foregoing history, and the limitations in most foreign process patent laws which are not present in S.1543, it is unfair to characterize S.1543 as plugging a "loophole" in U.S. Patent Laws which is not present in the patent laws of other developed countries. No foreign legislative histories have been produced by any of the proponents of S.1543 to support the argument (inherent in Question (1)) that these foreign governments deliberately or consciously retained their process patent laws for the purpose of giving greater protection to process inventions. Whether foreign countries are, in fact, giving greater protection to process inventions, would require a country-by-country analysis to determine the extent to which these foreign process patent laws are actually being used and the types of cases in which they are being used, particularly in view of the "direct product" limitation and the "presumption" limitation. No such analysis has been offered by any of the proponents of this legislation, despite their vast resources.

As noted in Mr. Engelberg's testimony, the patent laws of many foreign countries contain either a "working" requirement, a compulsory license requirement, or place some limitation on the ability of the patent owner to obtain an injunction against patent infringement if the patented invention is not being practiced by the patent owner in the country. It was Mr. Engelberg's contention that the "domestic industry" requirement in actions before the ITC under Section 337 was analogous to the foreign "working" requirement. The question of whether a particular country imposes a "working" requirement, a "compulsory license requirement", or a restriction on the grant of injunctions, is an issue which is separate from the scope of process patent protection provided in a particular country. For that reason, the ultimate conclusion which Question (1) seeks to reach is wrong. Any country which imposes a working requirement is operating in a manner which is analogous to an ITC proceeding.

Question (2) Why should working a process patent in this country be a prerequisite for protection against the use or sale by others in this country of the products of that patent? Why should there be a domestic working requirement for process patents with respect to importation of products made by that process, when there isn't a similar requirement for protection against the importation of patented products.

Answer to Question (2)

This legislation seeks to impose liability on the innocent U.S. buyers, users and sellers of unpatented products based upon the bare allegation that those products were produced abroad by a process claimed in a U.S. patent. Never before in the history o. U.S. Patent Law has liability for patent infringement (and the defense of litigation) been placed on a party who did not "make, use or sell" the patented invention, or actively induce or contribute to the infringement.

If the patented invention is a new process for making an old product, which is the usual case, the innocent U.S. purchasers and users of the unpatented product have no reason to suspect that any infringement has occurred, let alone any means of readily determining whether it has actually occurred. Under these circumstances, there is a strong possibility that unfounded charges of infringement will be asserted solely because the innocent and unknowledgeable buyers, sellers and users of products can be coerced into changing a source of supply, rather than being trapped in costly litigation which they have no means to defend. The use of the U.S. judicial system for such purposes violates fundamental notions of due process. Accordingly, expanded enforcement of process patents should not be legislated unless there are exceptionally strong countervailing public policy reasons and the legislation is amended to provide adequate safeguards to prevent the misuse of the judicial system.

The proponents of S.1543 argue that the legislation will create new jobs in the United States. If they are sincere

in that argument, then they should have no objection to amending the legislation in a manner which ensures that process patents will be domestically exploited in order to create those jobs. Process patents are currently protected against foreign infringement in the ITC pursuant to 19 U.S.C., but only if the owner of the U.S. process patent is actually practicing that patent in the United States. This "domestic industry" requirement clearly provides an incentive to the domestic exploitation of U.S. process patents. If S.1543 is not amended to contain a comparable "domestic industry" requirement, this important incentive to the creation of jobs in the United States will disappear.

One of the primary arguments made by the proponents of S.1543 is that the scope and content of foreign patent laws are relevant to the type of laws which should be enacted in the United States. Indeed, that is precisely the argument which is inherent in Question (1). If foreign patent laws are to serve as a model for our own laws, then it is appropriate to consider other sections of those laws, including those sections which recognize that patents can serve a useful purpose as an element of national industrial policy by imposing a "working" requirement or similar provision which limits the ability of the patent owner to enforce a patent if it is not exploited in the territory.

It seems particularly appropriate to consider the imposition of a "working" requirement or "domestic industry" requirement in proposed legislation which has been heavily promoted as a bill which would create new U.S. jobs. The fact that no comparable requirement exists under U.S. law for product patents is, at best, irrelevant to the question of whether such a requirement should exist as a quid pro quo for extra-territorial process patent enforcement on behalf of the foreign nationals who now obtain 42% of all patents issued by the United States Patent and Trademark Office. Indeed, at a time when Congress is considering a variety of proposals to strengthen U.S. industries against foreign competition, it may be worthwhile to consider amending the patent laws so as to limit the enforcement of patents which are not used to promote the creation and expansion of domestic industries.

Question (3) Why wouldn't it be possible for your contracts with your overseas suppliers to require them to submit to U.S. jurisdiction with respect to process patent infringement suits?

Answer to Question (3)

The sellers of goods in the international marketplace are not likely to agree to subject themselves to lawsuits in a foreign country where they do not understand the language, do not have a regular place of business, do not have employees, counsel, etc., unless the value of the business associated with a particular contract is so large that the risk of becoming entangled in litigation must be tolerated. This is certainly true with respect to actual or potential liability for claims unrelated to the patent laws, and there is no reason to suspect that foreign manufacturers would exhibit any different attitude with respect to complex and expensive patent claims. Indeed, in the typical situation where neither the foreign manufacturer nor the domestic buyer has any reason to believe that any process patents exist or are infringed, there would be a great reluctance to accept liability for the defense of unidentified, unidentifiable, and perhaps frivolous claims.

GPIA members do not normally have the economic leverage over their sources of supply which would permit them to be successful in requiring suppliers to defend U.S. litigation. Thus, requests for indemnification or for submission to U.S. jurisdiction are more likely to result in "drying up" sources of supply. This would occur even though there is no known process patent which might be asserted with respect to the sale of a particular product.

Under current law, a patent owner can commence an action in the ITC which will put the foreign supplier on notice of a

specific claim of infringement and will promptly result in an exclusion order barring the further importation of infringing material unless the supplier provides information necessary to defend the case. It makes far more sense to use this type of economic leverage in response to a specific claim of infringement than to disrupt international commerce by creating a system in which every international transaction, however small, produces potential legal entanglements of unknown dimensions.

If the approach suggested by Question (3) is a good idea, it should apply to all domestic claims arising out of all international transactions and not be limited simply to process patent infringement claims. In fact, such an approach to international trade is now being suggested in other legislation. See S.1655. We believe that any attempt to expand the jurisdiction of the U.S. Courts over foreign nationals simply because they sell products which ultimately reach this country will be met with a firestorm of protest from both domestic and foreign sources because of its potential for interference with free trade.

Question (4) The representative of the American Intellectual Property Law Association raised the point that U.S. process patent holders who suspect goods made using their process are being imported into this country, typically have no way of even identifying who the foreign manufacturer is--they can only see who is using and selling the goods in this country. Can you suggest a way, short of S.1543, to require the users and sellers in this country to disclose their foreign sources so that U.S. process patent holders who believe their processes are being violated can obtain jurisdiction over and bring suits against the foreign manufacturer who is directly responsible?

Answer to Question (4)

GPIA does not oppose legislation which would require its members to cooperate in identifying their sources of supply. It has that obligation under present law in cases brought in the ITC. However, in the ITC the suit is against the imported goods rather than against individual companies, and an independent evaluation of the infringement claim is made by the Commission and its investigative staff. These procedures clearly limit the ability of a patent owner to use a process patent for harassment purposes. It is certainly not necessary to shift the burden of proving non-infringement to the innocent purchaser or to make the innocent purchaser financially liable for some one else's act of infringement in order to gain access to information concerning the identity of the foreign source. Yet, these are the essential concepts embodied in S.1543.

We do not believe that the representative of the American Intellectual Property Law Association can document the position stated in Question (4)--at least not in situations involving pharmaceutical products. In the recent ITC ligitation involving indomethacin, the original Complaint filed by Merck identified essentially all of the foreign manufacturers, international brokers, and domestic purchasers who had any involvement in the manufacture, distribution, or purchase of bulk indomethacin. Merck apparently had no problem in obtaining this information in view of the existence of various international trade directories and catalogs which contain comprehensive listings of manufacturers, products, selling prices, etc.

Wholly apart from the foregoing, the U.S. Customs Service may assist patent owners by providing an import survey pursuant to 19 C.P.R. 12.39(a). Customs will provide the names and addresses of the importers of merchandise which "appear to infringe" a patent, on a monthly basis for a prescribed fee. See 19 C.P.R. 24.12(a)(3). According to a paper presented by Samuel Orandle, Senior Attorney, U.S. Customs Service at a June 6, 1985 meeting of the New York Patent, Trademark and Copyright Law Association, most of the surveys conducted under these regulations have been for drug and chemical companies.

AIPPI Journal, December 1984

Laws & Practice

Proposal on Introduction of Product Patent and Extension of Patent Term in Russian Patent System through Japanese Experiences on Such Issues

Kyoji Murayama*

Part I: Japan's Experience in the Adoption of Product and Pharmaceutical Patent System

[I] Introduction

There are three ways for protection of the invention relating to "Chemical" field, that is

1) Product Patent—a way of protecting a "*Chemical Substance*" *per se*,
2) Use Patent—a way of protecting "*Use*" of a Chemical Substance and
3) Process Patent—a way of Protecting "*Process*" for manufacturing a Chemical Substance.

Among such ways for protection of the chemical invention, it is universally admitted that the strongest way for protection is that by Product Patent, while under Process Patent System which provides patent protection only to the manufacturing process for a chemical substance, protection of a valued chemical substance, if researched and developed, is insufficient.

Here, some of the countries adopting Product Patent System and some of the countries adopting only Process Patent System are worldwidely enumerated in the following.

* Director of Patent and Trademark Division, Fujisawa Pharmaceutical Co., Ltd., Japan.
This paper was presented at the AIPPI conference held between U.S.S.R. Group and Japanese Group in Moscow on September 28, 1984.

Countries adopting Product Patent System where a Chemical Substance can be protected by Product Patent, Use Patent and Process Patent:

The American Area:

U.S.A., Canada*1), Cuba, Guatemala, Trinidad and Tobago, Haiti, Panama, Barbados, Argentina*1), Chile*1), etc.

*1) Note: provided that neither Product Patent is admitted to a chemical substance intended to be used for a medicine nor Use Patent for Pharmaceutical use of a chemical compound is admitted.

The European Area:

Ireland, Italy, The Netherlands, Greece*1), United Kingdom, Switzerland, Sweden, Denmark, West Germany, Norway*1), Finland*1), France, Belgium, Luxembourg, etc.

*1) Note: the same as above.

The Asian Area:

Australia, Hongkong, Japan, New Zealand, Philippines, Sri Lanka, Thailand*1), etc.

*1) Note: the same as above.

The Middle Asian Area:

Cyprus, Iraq*1), Iran*1), Israel, Turkey*1), etc.

*1) Note: the same as above.

The African Area:

Algeria, Zaire, Sudan, Burundi, Nigeria, Malawi, South Africa, Liberia, etc.

55 522 O - 86 - 5

Countries adopting only Process Patent System where a Chemical Substance can be only protected by Process Patent

The American Area:

Dominica, Mexico, Venezuela, Uruguay, etc.
Note: Brazil neither adopts product patent system nor process patent system.

The European Area:

[West] Austria, Spain, Portugal, etc.

[East] U.S.S.R., Czechoslovakia, Bulgaria, East Germany, Hungary, Poland, Yugoslavia, Romania, etc.

The Asian Area:

China*2), Formosa (Taiwan)*3), India, Korea*3), Pakistan, etc.

*2) Note: Patent Law will be in force on April 1st, 1985.

*3) Note: Adoption of the product patent system is now under study by the government.

The Middle Asian Area:

Kuwait, etc.

From the countries as enumerated above, it is observed that a product patent system is generally adopted in the advanced countries excepting the East European countries, but not adopted in the developing or middle developing countries.

Generally speaking, it is considered that a product patent system is reluctant to be adopted in the lower technically leveled countries from a standpoint of an industry policy, that is, an anxiety that the industries in such countries would be pressed by the foreign enterprises obtaining the product patents. In addition, a product patent system would be considered to lead to increased patented commodity prices and a fear is expressed that there could arise serious problem owing to monopoly of the commodities because there is a possibility that a company which has developed some chemical substance, e.g. a new drug covered by a product patent, would be in the position to dictate its output and price without regard to competition.

Under such possible problems, Japan adopted a product patent system from January 1, 1976 and it has passed about 8 years since then. Herewith, we wish to present a brief review of Japan's experieice in the adoption of product and pharmaceutical patent system in the following.

[2] Japan's Experience in the Adoption of Product and Pharmaceutical Patent System

The New Patent Law of Japan as amended June 25, 1975 went into force on January 1, 1976, proclaiming that chemical substances, pharmaceutical products, foods and beverages and articles of taste are also patentable. In this connection, we shall present below a brief review of Japan's experience in the adoption of a product patent system.

1. *Brief Review of the Circumstances Preceding the Adoption of Product Patent System in Japan*

1.1 The cradle in Japan's chemical industry

About a century ago, that was in 1885, Japan enacted and promulgated the Patent Ordinance which was her first patent law. While this Ordinance was essentially modeled after the Patent Law of France, it referred to pharmaceutical invention as an unpatentable invention and, in an invention of the chemical field, afforded protection to the production process only, not to the substance *per se*.

This patent law was amended in 1888, 1899, 1909 and 1921 in succession, but on none of the occasions was there a debate on the protection of chemical substance and pharmaceutical product, and the inventions of them remained to be unpatentable.

This status quo was occasioned by the following circumstances. As to chemical substance, since the chemistry was still young in the cradle, new processes of producing chemical compounds were on the way of research and development. Accordingly, the research activity was mainly directed to development of new processes of producing chemical compounds rather than to creation of new compounds, and the development of new processes of producing known chemical compounds was considered more important and given priority. As for pharmaceutical product, there was paid the general consideration that there should be avoided any problems such as the quantitative

restriction, price increase, etc. which patent monopoly eventually bring about.

Though the product patent system was theoretically needed even under the above circumstances, Japan dared to continue limiting patent protection to the production process without protecting the substance *per se*. In other words, in those days the invention of a process was considered to be more important and more meaningful than the invention of a chemical compound. Since a variety of novel and improved processes were conceivable for the production of a given compound, the process patent system well served its purpose by giving an adequate incentive to finding out new and improved processes.

1.2 The undesirable side of process patent system

However, the process patent system which had long been regarded by many as a worthwhile system began to prove out of line with demands of the age and cause the following adverse situations.

(1) At first, the inventive activity for new and improved process were extensively made and it appeared to anybody's eye that the process patent system was working successfully. However, as years went by, the inventions for such excellently improved processes tended to decrease in the number.

(2) The researches, besides the researches for the discovery of better processes, were directed to the invention of "detour" processes, intending to avoid patent infringement of the process patents owned by others, and such invention came forward in succession, such detour process being inferior and rather retrogressive in comparison with the already patented processes.

As the time elapsed, this trend grew up more and more to cause such an undesirable situation as the ill-use of the process patent system only to avoid the control of the existing process patents. Thus, the object of the process patent system *per se* had decreased its value.

(3) The extensive conducts of researches aiming at an invention of so-called "roundabout" or "detour" processes resulted in increasing a number of infringement actions in the court.

(4) There were imported a large number and quantity of chemical compounds allegedly to have been produced in a foreign country by processes (whether the processes are "improved" or "retrogressive" ones) different from those already patented in Japan, which increased the quantity of imports in total. Patent litigation cases also increased.

(5) The major research effort was directed to the development of processes for avoiding the infringement of others' patents and the basic research such as the research for creating useful and new compounds, which was demanded in the international field of advancing technology, was often disregarded. Consequently, the relative level of domestic technology for finding out new compounds became more and more depressed as compared with the levels in foreign countries.

(6) There arose many meaningless research competitions among companies which did not truly contribute to advancement of technology in the companies involved.

Thus, in order to fully protect his right, even the creator of a new chemical compound or his assign was forced to conduct useless research and development and file useless patent applications, with the result that his essential attitude toward research and development was often side-tracked and fruitful litigations arose one after another.

In the pharmaceutical industry, in particular, even research-oriented companies were forced to conduct a lot of useless researches in order to fully protect their new drugs.

(7) In regard of chemical processes as such, there became less and less room for innovations everywhere in the world, while many researches in the world were directed to new compounds or new uses for known compounds, so that the process patent system came to having not served this new current.

1.3 Moves to adoption of product patent system

(1) In 1955 and onwards, in order to overcome the above undesirable situation on the process patent system and also from international viewpoint, the necessity to promote progress of chemical technology had been keenly felt and, indeed, the time was ripe for a revision of the patent system.

Under the circumstances, for the purpose of investigating the possibility of revising the patent law along this line, the Japanese government (the Patent Office) in March, 1955 con-

ducted an opinion survey sending questionaires to 1352 companies, etc. including chemical manufacturers, chemical user companies using chemical compounds, universities, research institutions, academic circles, etc. The result was that the positive and negative responses were nearly even, among which 52.0% of the pharmaceutical manufacturers, 52.2% of the chemical user companies, 63.3% of the research institutions and 53.3% of the academic circles favored the adoptation of a product patent system.

(2) The 1959 Revision of the Patent Law.

In the questionnaire survey of 1955, positive and negative responses were nearly even, and the adoptation of product patent system was strongly voiced. However, in view of such a vital revision, government took a cautious attitude and a rush to adoptation of the product patent system was then withheld for the reason of prematureness in time. Thus, the matter was postponed till the next revision of the Law, this postponement having been ultimately repaid with a delay in the progress of technology. However, the government was watching for a good opportunity for adopting the product patent system, realizing that the voice on the affirmative side became higher and higher in the related business world so that the necessity of said system was felt more and more.

(3) The subsequent Development.

1) International Trend

In 1958 a conference for revision of the Paris Convention was held in Lisbon. The debated and discussions in this conference resulted in a recommendation to the effect that, in view that the maximum protection should be given to inventions in order to promote the progress of technology, the member countries should study the possibility of providing for the patent protection of new chemical compounds independently of production processes.

Thus, the time was truly ripe for the product patent system and, in pursuance with the spirit of the above recommendation, the Federal Republic of Germany adopted a product patent system at its revision of her patent law in 1968.

2) The 1970 Revision of the Patent Law

In 1970, the Patent Law was partially revised with improvement for making the same come nearer to the international level, which was mainly directed to an early disclosure of applications and an examination request system, the patent product system was not included in the bill to the Diet despite the keen

Table 1
Results of a Questionaire Survey relating to Adoption of Product and Pharmaceutical Patents (1970)

	Total pros and cons				Pros and cons; non-committals excluded		
	Yes		No	Non-committal	Yes		No
Product patent		59.6%	8.6%	31.8%		87.4%	12.6%
	Unqualified	6.0%			Unqualified	8.8%	
	Qualified	53.6%			Qualified	78.6%	
Pharmaceutical patent		38.2%	15.9%	45.9%		70.6%	29.4%
	Unqualified	5.2%	5.2%		Unqualified	9.5%	
	Qualified	33.0%	33.0%		Qualified	61.1%	

Notes:

(1) In terms of "total pros and cons", the percentage of those who favored the grant of pharmaceutical patents was as low as 38.2% but this was most probably because more than a half of the respondents were non-chemical companies which were naturally not much concerned with pharmaceutical patents. In fact, non-committals accounted for as many as 45.9%. In terms of "pros and cons, non-committals excluded", the percentage of those in favor of the system was as high as 70.6%.

(2) Those who favored the grant of product and pharmaceutical patents with some qualification demanded, for both kinds of patents, that the grant of patent be made with stringent criteria and that there be restrictions on the exercise of rights (for example, more liberal conditions for compulsory licenses).

demand for adoptation of the product patent system. However, the bill was passed with an additional resolution to the effect that efforts should be made to form a definite plan on chemical and pharmaceutical patents at the earliest possible data.

3) In response to the above additional resolution at the 1970 revision of the Patent Law, the Japan Patent Association conducted an opinion survey, i.e. the Questionaire Survey related to a Product and Pharmaceutical Patent System, sending questionaires to its 335 member companies. As shown in Table 1, the majority of the members favored the adoption of such a system.

However, as Table 1 shows, there were still some who opposed to the grant of product and pharmaceutical patents. However, these oppositions were not openly acknowledged. And the Japanese government, both the Ministry of Health and Welfare and the Ministry of International Trade and Industry combined, held the firm view that the product and pharmaceutical patent system was necessary not only for the growth of the individual companies but also for technological progress in the chemical and pharmaceutical industries.

4) Given the above impetus to revision of the patent system, "Product Patent Study Team" composed of representatives of the government (the Patent Office), the Japan Patent Association and the Chemical Industries Association of Japan was organized in 1971. The team visited the United States and European countries where they made a detailed study of the status and problems in respect of their product and pharmaceutical patent systems for the purpose of obtaining referential data for the adoption of a similar system.

1.4 Adoption of the product and pharmaceutical patent system

(1) The Japanese government (the Industrial Property Council) began to study and discuss the possibility of adopting a product and pharmaceutical patent system in 1971 and submitted a conclusion, in 1973, reporting that "a product patent system should be adopted." Based on this proposal, a bill for Revision of the Patent Law was draft and submitted to the Diet in 1975.

Oppositions to this bill were voiced by some of the small and medium companies and especially those not research-oriented. However, the Japanese government had by then been well aware of the absolute need to adopt a product patent system for encouraging the advance of technology in long-term prospectives. In fact, throughout the parliamentary session, there was not a single move against the proposal, even from the minority parties. This was because all the political parties of Japan thought that a product patent system should provide their chemical and pharmaceutical industries with a strong incentive to technical development.

Ultimately, on the 29th day of May, 1975, the bill for Revision of the Patent Law incorporating a product patent system passed the Diet. The law was promulgated on the 25th day of June the same year and became effective on the 1st day of January, 1976, giving patent protection to chemical substance and pharmaceutical product.

(2) Meanwhile, the validity of patent right on a chemical product invention extends to the production and use of the chemical substance, regardless of the process for its production or of its uses. Therefore if a product patent system be adopted the influence of such a right on third parties should be greater than it was when the 1975 patent law providing only for process patent and use patent (excepting pharmaceutical product, beverage and food) was in force. In order to lessen such influence, the following measures were taken to strike a balance between a chemical product patent and the third party's rights (a process patent, a use patent and a selection invention patent).

(a) Relation of a prior patentee to a later patentee

In case a later patented invention (a novel production process for the chemical substance patented by a prior patent, a novel use of the chemical substance patented by a prior patent, etc.) is one which utilizes a prior patented invention (an invention of the chemical product), the later patentee (a process patentee, use patentee, etc.) cannot effect the working of it's own patented invention (a production process or use) without the grant of a license from the prior patentee (a patentee for the chemical substance).

Therefore, it has been proved that: (i) a later patentee may, when the patented invention is one which utilizes the patented inven-

tion of a prior patentee, demand of the prior patentee a consultation as to the granting of an ordinary license for the prior patented invention, and (ii) when such consultation has not successfully been concluded or it is impossible to hold such consultation, the later patentee may demand the arbitration of the Director of the Patent Office as to the granting of an ordinary (non-exclusive) license for the prior patented invention.

Thus, the latter patentee could effect the working of its own patented invention.

(b) Relation of a prior patentee to a later patentee

In this connection, when a license for the working of the right (the one to produce or use the patented chemical substance) owned by the prior patentee (a chemical product patentee) is granted to the later patentee (a process patentee, a use patentee, etc.), the later patentee can enjoy the benefit as mentioned in the above (1). On the other hand, if the prior patentee cannot effect the working of the later patentee's right, i.e. the invention of a novel or improved production process or a novel use, the prior patentee (a chemical product patentee) who developed a novel chemical substance spending much labor and expense will have to sustain a great deal of loss and disadvantage. The prime purpose of affording protection to a chemical product invention is to give an incentive to a chemical product invention is to give an incentive to the development of a novel chemical substance, and therefore, if the interest of the patentee who invented a novel chemical substance is injured, the significance of adopting a chemical product patent system will be considerably lost.

In order to avoid the undesirable situation as mentioned above;

(i) It has been provided that in case the later patentee comes to demand of the prior patentee such a consultation as stated above, the prior patentee may demand of the later patentee a consultation as to the granting of an ordinary (non-exclusive) license for the working of the later patentee's patented invention, and

(ii) When this consultation has not successfully been concluded or it is impossible to hold such consultation, and also when a demand for an arbitration as mentioned in the above (a) (ii) is made (i.e. when the later patentee has demanded the arbitration of the Director of the Patent Office as to the granting of an ordinary license for the working of the prior patentee's patented invention), the prior patentee may also demand the arbitration of the Director of the Patent Office as to the granting of an ordinary license for the working of the later patentee's patented invention.

By this way, a balance was striken between the positions of the prior patentee and the later patentee in the form of cross licensing.

2. *Background and Necessity of Adopting a Product Patent System in Japan*

The above is a brief history of adoption of the product patent system in Japan, and the proposal was made with the understanding that the time was ripe for the adoption of the system in view of the moves in other countries and the trend toward an international unification of patent systems. Its background and necessity are outlined below:

2.1 Relation of process invention and use invention with the product invention

(1) Avoidance of meaningless Research and Development as well as unnecessary Conflicts

Under the process patent system which provided patent protection only to the production process for a chemical substance, protection of a valued chemical substance, if developed, was insufficient. Therefore, the person who created such chemical substance was obliged to make research and development for many production processes and to file many patent applications for the purpose of obtaining sufficient protection of his invention. On the contrary, the research activities of other persons than the first creator of the chemical substance concerned were mostly directed to the follow-up studies of the original invention. As a result, the real purpose of research and development was distorted, and conflicts took place often. Under the circumstances, there was strongly voiced a desire to avoid such meaningless research and development as well as such unnecessary conflicts.

(2) Research and Development for Production Process or Novel Use Inventions

There was a fear among some people concerned that adoption of a product patent sys-

tem might impede research and development for superior production process or novel use inventions. However, it was finally recognized that, even if a product patent system was adopted, once a valued novel chemical substance was produced and came to be known, an improved production process for the substance or its novel use would also be separately patented, and therefore that research and development for these inventions would not be impeded as far as these inventions were concerned with superior improved production processes or new uses.

(3) The Status of the Patentee Who Invented an Improved Production Process or a New Use

The later patentee who obtained a patent on a novel production process or novel use which is connected with the prior patented invention on a certain chemical substance cannot effect the working of his patented invention without obtaining a license for the working of the patented invention of the prior patentee (product patentee). However, when the later process patentee cannot obtain such a license (an ordinary license) from the prior product patentee even under reasonable terms and conditions, the later process patentee of improved process or new use can effect the working of his invention by demanding an arbitration for a license (non exclusive licence) as to the chemical substance concerned. Therefore, it was recognized that the later process patentee would never be adversely treated.

2.2 Relation with commodity prices

(1) It was once thought that a product patent system would lead to increased patented commodity prices. Actually, however, it was found that such a view was near-sighted and that the adoptation of a product patent system would not cause price increases.

The price of commodities is governed by a variety of factors. Though a product patent system may be one of the factors influencing the price, it can never be a determinant factor. The price of commodities is largely a function of the industrial and financial policies of the government.

Taking pharmaceutical products as an example, a survey of international drug prices revealed that the prices of drugs in the countries with a product patent system were not higher than those in the countries without such a system.

That the adoption of a product patent system will not cause price increases is apparent from German experience as shown in Table 2. There, the prices of pharmaceutical products were not particularly influenced by the adoption of the product patent system.

(2) A number of different drugs with equivalent clinical efficacy are available on the market. Under such circumstances, it was recognized that if the price of a drug protected by a patent is unreasonably high, the public will not use such an expensive drug but use some other equivalent drug, and therefore there was no problem in this respect.

(3) It was also recognized that if, for some reason or other, the price of a drug tends to increase beyond a reasonable level, the price can be controled by means of a compulsory license system from the standpoint of public interest.

2.3 Relation with the monopoly of commodities

Pharmaceutical products are indispensable to human life in view of their close relation to our health and hygiene. Though there are some drugs for almost any kind of disease today, there may arise the circumstances that

Table 2

Year	Drug price index (A)	Living cost index (B)	Real drug price index *1 (A/B x 100)
1962	100	100	100
1965	103.2	108.7	95
1966	108.7	112.7	96
1967	110.2	114.6	96
1968	112.7	116.4	97*2
1969	11.4	119.5	96
1970	120.5	123.5	98
1971	126.0	130.1	97
1972	132.0	137.2	95
1973	137.9	146.8	94
1974	150.5	159.1	95

Notes:
*1) The drug price index includes the cosmetic products.
*2) The year when the product patent system took effect.
(Wirtschaft und Statistik's data for December, 1963 to November, 1974)

even such drugs are not always sufficient. There may be anticipated the cases in which there is virtually not a substitute once a very effective drug having a specific efficacy is developed. This problem will be particularly serious if a completely new, effective drug has been created and developed for a disease for which no other effective drug is available.

In such a case, the company which had developed such a new drug will be in the possible position to dictate its output and price without regard to competition. In this sense, a fear was expressed that there could arise serious problems owing to monopoly of the commodities.

However, it was realized that, in such a case, the monopoly of commodities can be controlled by taking the proper measures as follows.

(1) In case the owner of a product patent monopolizes the working of the patented invention and does not make available a sufficient supply of the product (drug).

For such a patentee (enterprise), all that is necessary is only to pay attention to the size of demand and the maximum share of the market irrespective of production price (cost). Accordingly, it may pursue the maximum profit without regard to other factors, and therefore, there is the possibility not only of market monopoly but also of price increase. However, in this case also, it is possible to establish a non-exclusive license for reasons of non-working or, in certain cases, a non-exclusive license in the interest of the public. In addition, in the case of pharmaceutical products, the Ministry of Health and Welfare may order the company to observe a supply duty of the drug and to thereby prevent undesirable results.

(2) In case the owner of a product patent does not work the invention in Japan nor does it grant a license to a third person, supplies the drug only through importation and, moreover, control the import.

There is the possibility of market separation and price discrimination in this case. However, the evil results can be prevented by means of the demand for establishment of a non-exclusive license (the establishment of a compulsory license) for the reason of non-working of the patented invention.

2.4 Encouragement of research and development

For the progress of chemical and pharmaceutical industries, it is most important to encourage researchers in the field. It was recognized that the companies should be encouraged to invest more in scientists and their researches and that for this purpose, a product and pharmaceutical patent system would be the most effective and suitable means.

2.5 Others

(1) Some pharmaceutical companies had opinions that it was too early to adopt a product patent system. However, most of the oppositions were not based on any detailed study of how many years ahead they will be ready to accept a product patent system but were merely wishful, irresponsible arguments to maintain the status quo.

(2) The recommendation at the 1958 Lisbon conference for revision of the Paris Convention that the member countries should study the possibility of providing for the patent protection of new chemical products resulted in the advent of earnest studies and efforts, in many areas of the world, to adopt a product patent system.

3. *Recognition at Present Stage after the Adoption of the Product Patent System*

3.1 Research and development

The following is a brief review of the status of research and development following the adoption of the product patent system, limiting the subject to pharmaceutical products.

In the first place, the trend of research and development is said to be truly reflected on new patent applications as results of such endeavors. In this sense, the trend of patent applications prior to the adoption of the product patent system and that after the adoption are shown in ANNEXED DOCUMENTS 1 and 2.

It will be apparent from these tables that, while the figures for 1975 and before, of course, represent process patent applications only, the total number of the early publication of patent applications related to chemical substances and pharmaceutical products in 1977 (the year immediately following the adoption of the product patent system) accounted for

about 60% of the total number of the applications in these areas, and for about less 70% in 1978. In 1979 and onwards, the percentages are almost constant at about 70% and 77% in 1983. In contrast, the percentage of the early publication of the process patent applications was 40 to 34% during the initial years (1977–1978) and has since 1979 been constant at about 30% and 23% in 1983.

The above figures appear to indicate that research and development have been mostly concentrated into the development of new chemical substances.

However, the fact that the applications of production processes still account for about 23% of the total number of the applications seems to indicate that the importance of the process patents is also well recognized and the research and development for improved processes are not disregarded.

As a conclusion, it is believed that the product patent system of Japan is and will continue providing a strong incentive to her chemical and pharmaceutical industries.

3.2 Monopoly of commodities and price increases

There was initially a concern that the adoption of a product patent system would invite monopoly of commodities and price increases. However, actually, none of such results occurred.

(1) Regardiig pharmaceutical products, Japan as in the case of Germany did not see any real increase in the drug prices as a consequence of adoption of the product patent system. This is because the Ministry of Health and Welfare has the authority to determine the drug prices under administrative procedures.

Incidentally, recently, the Ministry of Health and Welfare has made it a rule to examine, against reasonable criteria, the prices of clinically equivalent drugs to see if they are reasonable or not. This is evidence that the product patent system is only one factor for deciding the price of commodities.

(2) Lastly, in regard to the monopoly of pharmaceutical products, the bad influence of monopoly has never been encountered since the adoptation of the product patent system. That is, a large variety of products for the treatment or prevention of the same disease are available in Japan at the present stage, probably as in the rest of the world. Therefore, the public has an option to select any desired drug from among a variety of products on the market for the same disease.

[III] Conclusion

The foregoing is a brief description of Japan's experience in the adoption of a product patent system. The product patent system is and will keep encouraging the researchers and companies to make inventions and thereby stimulating their volition to research and development. We believe that the system will contribute to further advances of technology in the chemical and pharmaceutical fields. It is also believed that these advancements are best assured by the product patent system.

As explained in Introduction of this article, we understand that the developing countries are anxious about a product patent system from a viewpoint of their technical levels which are much lower than those in the advanced countries and reluctant to adopt the same.

However, with respect to the technical level in the chemical industries including pharmaceutical industry, U.S.S.R. is no less high than the other advanced countries where the product patent system is adopted. Accordingly, we hope that U.S.S.R. will adopt the said system, which will give more incentive to the technical exchange in the chemical industries including pharmaceutical industry with some of the advanced countries, in the not so far distant future.

Part II: A Study of the Patent Term Problem

[I] Introduction

A patentee and its licensee have great concerns about the patent term, and the longer the patent term is, the more profit the patentee and its licensee could obtain from its patent, because they can enjoy a monopoly of their patented products for longer years. On the other hand, the public, e.g. consumer might prefer to the shorter term, because they may be released from a monopoly of the patented products at the earlier stage which would control the prices, qualities, etc. of such products. Accordingly, it is a matter of course that

a theoretical balance be taken into consideration between the interests of the patentee and the consumer, and such balance could be set up based on the social, economical and technical circumstances, etc. of each country. This is noted to be the reason why there is a variation in the patent term according to each of the countries.

Here, the writer would like to state an outline of the present situation on the patent term as fixed in the world and touch upon a problem on the patent term as now discussed in some countries, that is, patent Term Restoration in the following.

It is hoped that the reports as stated herein will be useful and serviceable for U.S.S.R. to study and review the patent term as now fixed in U.S.S.R.

[II] Variation in Patent Term in the World

The followings are the patent terms as fixed in some countries, which are classified according to the difference of the country area.

The abbreviation words in the following list, i.e. (A), (AC), (P) and (PU) bear the meaning as explained in the Note below.

Note:

(A) To be counted from the date of Application.

(AC) To be counted from the date of Application with Complete specification.

(P) To be counted from the date of Patent, which includes the date of grant and issue of the patent.

(PU) To be counted from the date of Publication after completion of the examination.

The American Area

[North and Middle]

Costa Rica: 20 (P)
Honduras: 10, 15 or 20 (P)
Cuba: 17 (P)
U.S.A.: 17 (P)
Dominica: 5, 10 or 20 (P)
Ehalvador: 5, 10 or 20 (P)
Haiti: 5, 10 or 20 (P)
Panama: 5, 10 or 20 (P)
Canada: 17 (P)
Guatemala: 15 (P)
Trinidad and Tobaco: 14 (P)
Barbados: 14 (A)
Mexico: 10 (P)
Nicaragua: 10 (P)

[South]

Bolivia: 15 (P)
Uruguay: 15 (P)
Argentina: 5, 10 or 15 (P)
Chile: 5, 10 or 15 (P)
Brazil: 15 (A)
Paraguay: 15 (A)
Colombia: 10 (P)
Equador: 10 (P)
Peru: 10 (P)
Venezuela: 5 or 10 (P)

The European Area

[West]

Spain: 20 (P)
Belgium: 20 (A)
Denmark: 20 (A)
Finland: 20 (A)
France: 20 (A)
W. Germany: 20 (A)
Italy: 20 (A)
Luxemburg: 20 (A)
Holland: 20 (A)
Norway: 20 (A)
Switzerland: 20 (A)
Sweden: 20 (A)
United Kingdom: 20 (A)
Austria: 18 (P)
Ireland: 16 (AC)
Portugal: 15 (G)
Greece: 15 (A)

[East]

Hungary: 20 (A)
E. Germany: 18 (A)
Bulgaria: 15 (A)
Czechoslovakia: 15 (A)
Poland: 15 (A)
Romania: 15 (A)
U.S.S.R.: 15 (A)
Yugoslavia: 7 (PU)

The Asian Area

Philippines: 17 (P)
Australia: 16 (AC)
New Zealand: 16 (AC)
Pakistan: 16 (A)
Sri Lanka: 15 (P)

Korea: 12 (PU) but < 15 (A)
Japan: 15 (PU) but 20 < (A)
Formosa: 15 (PU) but 18 < (A)
China: 15 (A)
Thailand: 7 or 15 (A)
India: 14 (P)

The Middle Asian Area
Israel: 20 (A)
Iran: 20 (A)
Iraq: 15 (A)
Kuwait: 15 (A)
Lebanon: 15 (A)
Syria: 15 (A)
Turkey: 5, 10 or 15 (A)

The African Area
Liberia: 20 (P)
Botsuwana: 20 (AC)
Zimbabwe: 20 (AC)
Algeria: 20 (A)
Burundi: 20 (A)
Nigeria: 20 (A)
South Africa: 20 (A)
Sudan: 20 (A)
Tunisia: 20 (A)
Zaire: 20 (A)
Malawi: 16 (AC)
Zambia: 16 (A)
Egypt: 15 (A)
OAPI: 10 (A)

From the countries as enumerated above, it is observed that the patent terms are longer in the advanced countries except the countries in the East European Area than those in the developing and middle developing countries, with some exception (e.g. some of the Middle American Area and African Area).

For example, the patentees can enjoy their patent rights at least for 20 years from the date of application in most of the West European Area, U.S.A.*, Canada*, Japan**, etc., while the patent terms are around 15 years and below from the date of application in most of the East European Area, The South American Area, Formosa, China, Korea, etc.

Note:

* In these countries, the patent terms would become 20 years and more because it takes usually around three years for completion of the examination and the issue of patent.

** In Japan, the patent term would become 20 years, if a request for the examination is filed within around three years after the application date, because it takes usually 2 years and more for completion of the examination and the publication.

It is understood that there are some differences of the patent term among the countries due to various circumstances in each of them. Nevertheless, in consideration that the technics are international and the Industry Property Right is to be a right promised in the international system for protecting the inventions worldwidely, it seems to be ideal and substantially preferable that the duration period of such right shall be harmonized through the world.

Apart from the above discussion, the problem on the period of patent protection has been debated for recent several years in the field of fine chemical industries, e.g. pharmaceutical, agricultural industries, etc. In this respect, for better understanding the writer wishes to borrow the following sentences from the booklet titled "Intellectual Property Rights and Innovation" presented to Parliament by The Prime Minister by Command of Her Majesty December 1983 as follows.

> "It is not self-evident that the period of patent protection should be the same for all areas of invention. There are major differences in the scale of research and development needed for advance in different subjects. The theoretical balance between the interests of the consumer and the producer could be set at a different level for some products by giving a shorter period of monopoly (as India does for food and medicines). Conversely for those products which are delayed from entering the market by lengthy *Government regulatory procedures*, (medicines again) the period of patent monopoly might *be extended to compensate*. The most sustained case for variable term is presented by pharmaceutical companies for patent term extension. They claim that regulatory procedures can halve the useful lifetime of a patent (i.e. after launch of a product into the market place)".

Then, the writer will touch upon the present

Process Patent Protection in Group B Countries

Country	Process Patent protects its direct product	Importation constitutes infringement	Presumption in favor of process patentee
Austria[1]	yes		yes[2]
Belgium[1]	yes[3,4]	yes	
Canada	yes[3,4]		yes[2,4]
Cyprus[5]	yes	yes	
Denmark	yes	yes	
Finland	yes	yes	
France[1]	yes	yes	
Federal Republic of Germany[1]	yes		yes[2]
Great Britain[1]	yes	yes	
Greece	yes		yes[2]
Holy See[6]			
Iceland	yes	yes	
Ireland	unclear[3,7]		
Italy	yes		yes[2]
Japan	yes	yes	yes
Liechtenstein[8]	yes		yes
Luxembourg[1,9]	yes[4]		
Monaco[6]			
Netherlands[1]	yes		yes[2]
New Zealand	yes[4]		
Norway	yes	yes	
Portugal	yes	yes	
San Marino[10]	yes		yes[2]
South Africa	yes		yes
Spain	yes	yes[4]	
Sweden[1]	yes	yes	yes[2]
Switzerland[1]	yes		yes
Turkey[9]			
United States of America			

1 EPC member.
2 Applies to new substances only.
3 No clear statutory provision.
4 Apparently applies in at least some situations.
5 Registration in Cyprus of a United Kingdom patent confers the same rights in Cyprus.
6 No patent law.
7 Claims are permitted, but legal issues are apparently unsettled.
8 Liechtenstein and Switzerland constitute a single territory for patent purposes.
9 No copy of the national law was available.
10 Industrial property rights acquired in Italy are valid in San Marino and vice versa.

Senator MATHIAS. Ms. Buc, all of that bell-ringing means that I have got to take another jog. So if you will withhold your statement, I will be back as quickly as I can. I apologize, but it is beyond my control.

[Short recess.]

Senator MATHIAS. I think the record ought to show that my turnaround time was faster on that vote. If we keep on going, why, I may get to be in shape.

Ms. Buc.

STATEMENT OF NANCY L. BUC

Ms. BUC. Good morning, Mr. Chairman. My name is Nancy L. Buc, and I am a partner in the firm of Weil, Gotshal & Manges. My statement today is presented in behalf of the National Association of Chain Drug Stores.

I very much appreciate the opportunity to testify this morning and to discuss NACDS' position on this bill.

I want to emphasize the word "this," Mr. Chairman, "this" bill, because NACDS does join you in your concern for protecting U.S. intellectual property. We are not opposed to improvements in the enforcement of U.S. process patents.

Our problem with this bill arises with the possibility that it creates for e broiling retail drugstores in a literally impossible situation. The a erage chain drugstore has some 10,000 square feet of selling space and it offers more than 12,000 different products for sale to consumers. S. 1543 makes virtually every one of those 12,000 products, whether it is foreign or domestic, into a potential lawsuit. Under this bill, the mere filing of the lawsuit makes the retailer liable for damages, starting then and there, even though the retailer has no way of knowing whether it is infringing or not and cannot necessarily even find out. So the retailer has to play "process patent roulette." It either has to risk a substantial damage award, or discontinue the sale of the product. And what is more, the retailer has to choose fast, before the court renders a decision, before the plaintiff has even put on a case.

Under current rules of pleading, as you well know, the owner of a process patent can make a charge of infringement on information and belief. Lawyers are well aware that "information and belief" is not proof; it is just enough of an informed guess to make it ethical to file a lawsuit. Lots of plaintiffs who can ethically file a lawsuit cannot win it, and lots of them cannot even survive a motion for summary judgment.

But the retailer's liability under this bill does not await the testing of information and belief. It crystallizes immediately on the filing of the lawsuit.

A retailer's choice to drop a product instead of gambling on the outcome of process patent infringement litigation harms the retailer, of course, for the retailer loses the continuity of supply that is so essential to ordinary commerce. Competition and consumers will suffer, too, for S. 1543 is a wonderfully potent way to knock out competition. There is no real need to compete on quality or price; you just file an infringement case.

I am going to keep this short, Mr. Chairman, because I think you will hear a great deal more about the benefits and disadvantages of what the owners of process patents and manufacturers ought to be doing to each other.

NACDS' concern is from the retail standpoint and what they need to know is why this bill has such a short fuse and is so one-sided. Why not wait to see who wins before imposing damages? Why not reimburse retailers for their costs of defending these cases, including attorneys' fees, if plaintiffs lose? And most especially, why not require the process patent holder to fight its fight with the real party at interest—the allegedly infringing manufacturer—whether in a section 337 proceeding before the ITC, or in a U.S. district court, let the U.S. patentee deal directly with its real opponent. Let the parties directly involved, who know the facts, resolve the issue. But do not force chain drugstores or any other retailers to fight against coercive litigation in a fight that is not properly their fight.

Thank you.

Senator MATHIAS. Thank you very much.

[Ms. Buc's submissions for the record follow:]

PREPARED STATEMENT
OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.

SUMMARY OF TESTIMONY REGARDING S. 1543

1. NACDS is opposed to the Process Patent Amendments of 1985 because the legislation would make suspect all products offered for sale in a retail store.

2. Retailers have no way in which to ascertain the validity of a product and the processes used to make the product.

3. The legislation would be very disruptive to commerce and would make retailers vulnerable to expensive and complicated litigation.

4. S. 1543 would have a chilling effect on retail drug stores that dispense quality, less costly generic prescription drugs to patients and needy recepients.

* * *

Mr. Chairman and Members of the Subcommittee, my name is Nancy L. Buc and I am a partner in the law firm of Weil, Gotshal & Manges. My statement today is presented on behalf of the National Association of Chain Drug Stores (NACDS).

Founded in 1933, NACDS represents the management of 172 corporations that operate more than 18,000 retail drug stores and pharmacies throughout the United States. The chain drug industry currently employs more than one million people who work in corporate headquarters, regional offices, warehousing facilities, and retail drug stores. Annual sales for chain drug stores total about $25 billion, and that figure represents approximately two-thirds of all retail drug store sales in America. Corporate drug stores also account for one-third of all out-patient prescription drug sales in the United States.

On behalf of the NACDS membership, I very much appreciate the opportunity to testify at these hearings on S. 1543, the Process Patents Amendments of 1985, to explain why NACDS so vigorously opposes this bill. This bill would, if enacted, cast a black cloud over every product on retailers' shelves. The average chain drug store is some 10,000 square feet

in size and it offers more than 12,000 different products for sale to consumers. S. 1543 makes virtually every one of those 12,000 products, foreign or domestic, into a potential lawsuit. If there is a problem with process patent enforcement, it's hard to imagine a worse solution.

Under S. 1543, any holder of a U.S. process patent who thinks a retailer is selling a product made by an infringing process can sue the retailer for patent infringement. The mere filing of the lawsuit makes the retailer liable for damages starting then and there, even though the retailer has no way of knowing whether it is infringing or not, and can't necessarily even find out. So the retailer must play process patent roulette - it must either risk a substantial damage award or discontinue the sale of the product. What is more, the retailer has to choose fast - before the court renders a decision, before the plaintiff has even put on a case. Forcing the retailer to choose so early gives all the advantage to the plaintiff, and makes even a somewhat casual lawsuit advantageous to plaintiffs.

It will be said, of course, that there are safeguards against casual lawsuits, but the supposed safeguards don't offer much real solace. For one thing, under current rules of pleading, the owner of a process patent can make a charge of infringement "on information and belief." Information and belief isn't proof, it's just enough of an informed guess to make it ethical to file a lawsuit; lots of plaintiffs who can ethically file a law suit can't win them, and lots of them can't even survive a motion for summary judgment. Yet the retailer's liability does not await the testing of information and belief; it crystallizes immediately on filing. And retailers don't take much comfort in the availability of sanctions under Rule 11 for infringement actions brought in bad faith. S. 1543 plaintiffs can cause serious trouble even if they're in good faith, and most retailers won't go to the expense and trouble of proving bad faith.

It will also be said that this bill only makes retailers liable for failure to do what they should do anyhow - exercise their "leverage" over their suppliers. The retailer's vaunted leverage is largely mythical, for it is the very essence of retailing that no one product looms very large in the product mix. Moreover, most chain druggists, like most retailers, lack expertise in manufacturing in general. Remember, the average chain drug store stocks some 12,000 products. With 12,000 products in stock, the chain druggist would have to police 32 manufacturing processes a day, 365 days year, just to stay even.

Policing process patents is especially difficult. In most cases, there are a multitude of processes which could have been used to manufacture a particular product, and most of those processes would not involve infringement of the asserted patent. Nevertheless, under the proposed law, by merely making the allegation of infringement and putting the retailer of the product on notice of the claim of alleged infringement, the retailer becomes immediately liable for damages.

In any event, even if retailers could police a few process patents here and there, it is horribly inefficient and therefore very costly to police a marketplace at the downstream stage. Requiring the process patent holder to go head to head with the real party in interest, the allegedly infringing manufacturer, would be cheaper, faster, and more practical.

A retailer's choice to drop a product instead of gambling on the outcome of process patent infringement litigation harms the retailer, of course, for the retailer loses the continuity of supply so essential to ordinary commerce. Competition and consumers will suffer, too, for S. 1543 is a wonderfully potent way to knock out competition - no need to compete on quality or price, just file an infringement case. Indeed, the very reason for the charge of process patent infringement will be a desire by the patent owner to get the customers to buy the patent owner's product rather than the

allegedly infringing product. Thus, the legislation is designed and intended to promote the use of the coercive patent infringement litigation to alter the purchasing decisions of innocent customers in the chain of distribution.

When it comes to prescription pharmaceuticals, the ill effects of S. 1543 would be felt not only by consumers but by the State and Federal governments which finance Medicaid and Medicare. This is so because S. 1543 is, in fact, a blunt club which will be used to hit one of the most pro-competitive and cost effective elements in our health care system, generic drugs.

As the Subcommittee already knows from its deliberations in the 98th Congress in fashioning the Patent Restoration/ANDA Law, generic drugs are a safe, effective, and low-cost alternative to the usually more expensive brand-name prescription drugs. Pharmacists, senior citizens, labor organization and consumer groups have all supported enthusiastically the expanded use of generics and the relaxation of state laws and federal policies that would restrict the full use of these important medications. Today, the pharmacy department of a typical chain drug store stocks in inventory between 2,000 and 3,000 different prescription drug products, of which a significant number are generics. More and more generic drugs will be coming into the marketplace in the near future as a result of the landmark Patent Restoration/ANDA bill.

Generic drugs offer the potential for significant savings in health care costs, whether those costs are borne by individuals, insurers, employers, or the state or Federal governments. Indeed, major employers like Chrysler, numerous insurers, and States like Connecticut are offering incentives to patients who use pharmacists who dispense generic pharmaceuticals. Also, the Department of Health and Human Services is seriously considering generic incentives. If S. 1543 is enacted, all these initiatives will be at risk, for a pharmacy doing its best to provide patients with low-cost, high-quality

pharmaceuticals will surely be faced with process patent infringement cases, and will either have to raise prices so as to be able to afford to defend the cases or stop handling lawsuit-prone generic drugs. Either way, the public loses.

In conclusion, Mr. Chairman, NACDS members want to know why this bill has such a short fuse and is so one-sided. Why not wait to see who wins before imposing damages? Why not reimburse retailers for their costs of defending these cases, including attorneys fees, if plaintiffs lose? Most especially, why not require the process patent holder to fight its fight with the real party in interest, the allegedly infringing manufacturer? Whether in a Section 337 proceeding before the ITC or in a U.S. district court, let the U.S. patentee deal directly with its real opponent. Let the parties directly involved, who know the facts, resolve the issue. But do not force chain druggists to face coercive litigation in a fight that is not properly their fight.

Thank you.

WEIL, GOTSHAL & MANGES
A PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS

(202) 682-7000
N.Y. TIE-LINE (212) 431-6820
TELECOPIER (202) 289-7502
(202) 789-0084
TELEX ITT 440045

1101 FOURTEENTH STREET, N.W.
WASHINGTON, D.C. 20005

NEW YORK OFFICE
767 FIFTH AVENUE
NEW YORK, N.Y. 10153
(212) 310-8000
TELECOPIER (212) 752-3978
(212) 758-0173
CABLE WEGOMA
TELEX ITT 424281
ITT 423144

FLORIDA OFFICE
800 BRICKELL AVENUE
MIAMI, FLORIDA 33131
(305) 579-9500
TELECOPIER (305) 374-7159

NANCY L. BUC
DIRECT LINE (202) 682-7100

December 9, 1985

BY HAND

Senator Charles McC. Mathias, Jr.
United States Senate
Committee on the Judiciary
Subcommittee on Patents, Copyrights,
and Trademarks
Washington, D.C. 20510

Re: S. 1543, Process Patent Amendment of 1985

Dear Senator Mathias:

In response to your letter of November 15, I am enclosing NACDS' responses to questions 3, 4, 5, and 6.[1] I would also like to reiterate that NACDS does not oppose extending patent protection to holders of process patents. Its concern is simply the unfair burden which S. 1543 places on retailers. It would be far more equitable, as well as more efficient, to have the real parties in interest, the holders of the process patents, deal directly with the manufacturers of products which allegedly infringe their process patents.

On behalf of NACDS, let me again express appreciation for the opportunity to testify at the October 23 hearing and for this opportunity to respond to your additional questions.

Sincerely,

Nancy L. Buc

Enclosure

1. Questions 1 and 2 apply to issues of process patent law and policy which Mr. Engelberg's testimony covered, and to which I believe he has already responded. Accordingly, NACDS does not address them.

QUESTION 3 - Why wouldn't it be possible for your contracts with your overseas suppliers to require them to submit to U.S. jurisdiction with respect to process patent infringement suits?

It is not always necessary to rely on contractual agreements in order to bring foreign manufacturers into a United States district court to defend a process patent infringement suit. As you know, a court may exercise personal jurisdiction over a nonresident defendant so long as there are sufficient "minimum contacts" with the forum State "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice'."[2] In World-Wide Volkswagen, the Court relied on International Shoe in articulating its "stream of commerce" theory. "The forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State."[3]

The California Supreme Court recently relied on World-Wide Volkswagen's "stream of commerce" theory in holding that the exercise of personal jurisdiction in a product liability suit over a foreign manufacturer of component parts was fair and reasonable where that manufacturer introduced its products into the stream of commerce with the expectation that those products would be incorporated into finished products sold to consumers in the forum State.[4] The court reasoned that even though the

---

2. International Shoe Company v. Washington, 326 U.S. 310, 317 (1945) (quoting Milliken v. Meyer, 311 U.S. 457, 463 (1938)). International Shoe, of course, applied the due process clause of the Fourteenth Amendment to the jurisdictional reach of a state court. It is generally agreed, however, that the "fairness" analysis of International Shoe and its progeny is substantially similar for purposes of Fifth Amendment due process analysis in cases involving claims arising out of federal law, such as patent infringement. See Honeywell, Inc. v. Metz Appartewerke 569 F.2d 1137, 1143 (7th Cir. 1975); Cryomedics, Inc. v. Spembly, Limited, 397 F.Supp. 287 (D. Conn. 1975).

3. World-Wide Volkswagen Corporation v. Woodson, 444 U.S. 286, 297-298 (1980).

4. Asahi Metal Industry Co., Ltd. v. Superior Court of Solano County, 39 Cal 3d 35, 216 Cal Rptr. 385 (1985), petition for cert. filed, 54 U.S.L.W. 3330 (U.S. Nov. 12, 1985) (No. 85-693).

foreign manufacturer of the component parts had no direct contact with California, the constitutional requirement of "minimum contacts" was satisfied where the manufacturer was aware that a substantial number of its products would be sold in California. Additionally, even though the foreign manufacturer had been named as a defendant not by the plaintiffs, but instead in a cross-claim for indemnification by the primary defendant (i.e., the foreign purchaser of the component parts), the state's interest in protecting its consumers was sufficiently strong to render the exercise of personal jurisdiction "fair and reasonable."

In like fashion, once Congress establishes a cause of action regarding foreign infringement of U.S. process patents, the holder of a U.S. process patent could assert a district court's personal jurisdiction over a foreign manufacturer who may be infringing that holder's process patent when that manufacturer is aware that a substantial number of its products are going to be sold in the United States. Surely it is more consistent, to use the Court's words, with "traditional notions of fair play and substantial justice" to require the allegedly infringing manufacturer to defend its actions than to impose liability on a retailer for infringing a process patent of which he may not even be aware. Exercising personal jurisdiction in this manner brings the real parties in interest, the plaintiff and the alleged infringer, into court. Innocent bystanders, such as retailers, would then rightly be out of the picture.

Question 4 - The representative of the American Intellectual Property Law Association raised the point that U.S. process patent holders who suspect goods made using their process are being imported into this country, typically have no way of even identifying who the foreign manufacturer is--they can only see who is using and selling the goods in this country. Can you suggest a way, short of S. 1543, to require the users and sellers in this country to disclose their foreign sources so that U.S. process patent holders who believe their processes are being violated can obtain jurisdiction over and bring suits against the foreign manufacturer who is directly responsible?

First, the owner of a U.S. patent who believes that

infringing products are being imported into the U.S. may obtain a survey from U.S. Customs of importers of such allegedly infringing products, pursuant to 19 C.F.R. § 12.39(a). We do not see any obstacle to providing for similar surveys concerning foreign suppliers of products which may infringe U.S. process patents. U.S. Customs collects information concerning purchasers and sellers of merchandise on the invoices that accompany imported merchandise. See 19 C.F.R. § 141.86(a)(2), (b).

Second, S. 1543 could be amended to exempt from potential liability a retailer who supplies process patent owners with information concerning the retailer's foreign suppliers, upon receiving from the patent owner adequate assurances to the effect that such information will be kept confidential and will not be used for other purposes without the retailer's consent.

Question 5 - According to some witnesses at the hearing, retailers are already in the predicament of having to keep track of myriads of patents in order to assure themselves that they are not carrying merchandise that infringes product patents. You indicated S. 1543 would thrust this predicament on you for the first time. Would you please respond to this point?

The question indicates a misunderstanding of our concern. The problem with requiring retailers to keep track of process patents is that such a requirement gives no attention to the enormous costs involved in keeping track of foreign manufacturing processes to determine whether they infringe U.S. process patents. As the Subcommittee is aware, it is very difficult - usually impossible - to know from inspecting the product whether a process patent may have been infringed.

Question 6 - Would the National Chain Drug Store Association support the bill if it were confined to pharmaceuticals and industrial chemicals (thus excluding the thousands of consumer products you say would come into jeopardy under S. 1543 currently drafted)?

So long as the bill's provisions impose liability on retailers for selling articles which allegedly infringe

process patents, NACDS will have problems with the bill. Even if the scope of the bill is narrowed, retailers will still have to face unfair liability and bear the unfairly heavy costs of policing products and monitoring foreign suppliers' activities subject to the bill.

NACDS is not opposed to protection of process patents. What it opposes is making the chain drug industry and other retailers liable in situations where they are not the real parties in interest.

Senator MATHIAS. Now, as I see one of the points you are making here, the question is whether there is prospective damage or whether, retrospectively, you prove that there has been damage under the existing law. Is that it, Mr. Engelberg?

Mr. ENGELBERG. I am not sure I understand the statement. I think if what you are saying is whether or not there should be liability from the moment of notice versus liability from the moment of decision, I think that is an issue that Nancy Buc addresses and that I have addressed and that we are both concerned about.

Senator MATHIAS. Under the present law, there is a kind of retrospective remedy. In other words, you have to prove that there has been a violation, an infringement, and that there has been a damage.

Mr. ENGELBERG. Under present law, when one takes into account the statute of limitations that applies to patents, a suit for patent infringement—and this bill does not purport to change that in any way—a suit for patent infringement can be brought at any time within 6 years of the act of infringement, and liability attaches for all of the acts that occurred within the 6-year period.

So, hypothetically, a retailer or someone in the chain of distribution with absolutely no knowledge that there is any process patent, could be sued and would be liable. Now, one of the amendments to this bill was you would not be liable until you actually got notice——

Senator MATHIAS. Yes, I should have been more specific. I was thinking of the ITC injunction.

Mr. ENGELBERG. Oh, in the ITC, one has to be a little careful. Yes, the relief is prospective only, in that the Exclusion Order, which is the major remedy which the ITC deals in, does not become effective until the Commission decides the case—with some exception, because the ITC has developed a doctrine that says that you cannot stockpile goods—in other words, you cannot in anticipation of losing the case bring in huge amounts of goods out of the ordinary course of business, in the hope of escaping the purpose of the Exclusion Order. So in that sense, the ITC does have some retroactive jurisdiction which it exercises.

Senator MATHIAS. Yes, that was the thought I had.

But then there is the other point that you made that under the ITC procedures, it is necessary to prove damage to a domestic industry.

Mr. ENGELBERG. As interpreted in patent-based cases under section 337, while the language of the statute speaks in terms of "an efficiently and economically operated domestic industry" and "substantial injury or tendency to injure," the cases come out, one, that no patent owner has ever been tossed out of the ITC for being inefficiently operated; in fact, in the Allied case, there was a finding that prices were too high, that it was a money-losing operation, and Allied really needed to lower its prices if it wanted to have any market, and there was still a finding that there was a domestic industry, because they had a business here and they were producing here.

As far as injury is concerned, the only thing that has to be proved is that there is some loss of sales. And it is not a major hurdle. There has been one case, and there has been a lot of discussion about that case in relation to this bill, which is the Corning litigation——

Senator MATHIAS. But your point is that under the bill if that became law, you would not even have to show that.

Mr. ENGELBERG. A patent owner, under the normal patent damage provisions which would apply here—because what you are doing is amending the patent statute, and you are not proposing any amendment to the damage provisions—the infringing defendant would be liable for the provable damages, but no less than a reasonable royalty, I believe is what the statute says, and the cases say that can be anything from lost profits to lost sales to whatever traditional measures of damages are used in litigation in general.

Senator MATHIAS. How many products that are sold in a chain drugstore would be affected by a process patent proceedings before the International Trade Commission under section 337?

Mr. ENGELBERG. All of them. The chain drugstores sell all kinds of packaged goods, they sell all kinds of plastic products, they sell all kinds of paper good. All of these products are susceptible to being protected by process patents. In fact, Senator, most process patents cover old products, not new ones.

Senator MATHIAS. Can you think of any specific cases where, in fact, a chain drugstore has been cut off from a foreign supplier because of an ITC injunction?

Mr. ENGELBERG. A chain drugstore?

Senator MATHIAS. Or any drugstore.

Mr. ENGELBERG. In today's world where chain drugstores sell everything from toys to audio equipment, I would say that, essentially, every ITC case involving consumer goods—and there have been many involving videotape and video games and things like that—have resulted ultimately in the exclusion of products that went to chain stores and chain drugstores as well as other department stores of various types.

Senator MATHIAS. Do you want to add anything to that, Ms. Buc?

Ms. BUC. I think that is right. There is a tendency to think of a chain drugstore or any drugstore as carrying only pharmaceuticals. One of the problems with this bill, as is stated in my testimony, is

that they carry about 12,000 different products; they are as likely to be imported as not; they as likely to be subject to a process patent as not. What that means is that if the ITC finds a violation and excludes the goods, the chain drugstore will be cut off. But it helps to illustrate the difficulty of knowing anything about the process patents when you have 12,000 products. That is a lot of policing to do downstream at the retail level.

Senator MATHIAS. But if in fact ITC injunctions have issued which have cut off retailers from their foreign suppliers, how will the situation change dramatically under S. 1543?

Ms. BUC. Well, from our standpoint, the difference is dramatic. The retailer is not involved. That is the paradigm of what we think is desirable here, which is "lets you and him fight." Those are the people who know what the real facts are and what the real issues are. And having that proceeding at the ITC means that the retailer remains what it ought to be, which is an innocent bystander who is not financially involved in the debate. If the goods are cut off, they are cut off. If they are not cut off, they are not cut off. But it is not the retailer who is financing the litigation. It is the real parties at interest.

Mr. HADDAD. But you also have a screening process, you have a mandatory deadline, and you have a damage situation which is acceptable. So you really have a different set of circumstances when you go before the ITC.

Mr. ENGELBERG. Senator, one point that I think has not been highlighted well enough is that in the ITC, because the suit is against the goods, and in fact all goods of the description coming within the patent, and because the ITC does not have the personal service and venue problems that a district court has when you are operating one plaintiff against one defendant, there is a bringing together of people and information in a way that is likely to shed the most light on the issue and also because of the ITC's procedures, to do it in the most expeditious way.

In contrast to that, a process patent infringement one-on-one, one patent owner against one retailer or down-the-line distributor, there can be a 100 reasons why that suit is not worth defending, or why the foreign manufacturer might choose not to disclose or participate. He is not going to lose his whole market; he is going to lose one case in one jurisdiction and not on the merits.

So we have a coercion factor here that I think is really at the heart of our objection, and that is, how do you give reasonable protection to processes and reasonable protection to the people who are going to be sued who cannot defend themselves. So far, the answer is that the ITC is there, and it works, and in fact, the ITC was developed, as I said in my original statement, as a jurisdiction to deal with that problem. Now we seem to be just pushing the pendulum all the way to one side, and there does not seem to be a real clear reason why that is necessary.

Senator MATHIAS. Well, of course, Ms. Buc's answer demonstrates part of the problem. She said because the retailer is really cut out of liability under the existing law.

Ms. BUC. As it should be.

Senator MATHIAS. As it should be. But that brings to mind the case of the summer stock company that was playing Shakespeare's

"Hamlet," and an old ham actor was working his way through the greatest lines of "Hamlet" and doing it with such enormous gusto that within a matter of a few minutes, the audience was booing and hissing and would have thrown vegetables if they had had any at hand, and this old ham came out to the edge of the stage and said, "Wait a minute, wait a minute, don't boo me; I did not write these lines."

So you are saying that the retailer should be in that position.

Ms. BUC. Exactly. If we are hams, we are hams. I think that is exactly right. We did not write these lines. And the notion that retailers can somehow police all of their 12,000 suppliers for everything that somebody wants to police them for is beguiling, but I think it is misguided. The retailer is not really the real party at interest, and this bill makes the retailer much more of a party at interest than it ought to be economically or logically or legally.

We are not opposed to some sort of bill for process patent protection, but not one that embroils us in other people's fights.

Senator MATHIAS. Well, now, couldn't you cope with this situation in a different way? You fear that a patentee may sue without any reason to think that the process has actually been infringed, but in order to intimidate the importer into cutting off the overseas supplier. Is that what you mean by coercion?

Mr. ENGELBERG. Well, I think, and I think the proponents of this legislation have acknowledged this to be true, and that is that in an awful large number of situations, a common situation, there could be two, three, four possible processes which are being used. In the high-technology situation, it may only be one. But if there is more than one, neither side knows whether there has been infringement.

Senator MATHIAS. What about rule 11 of the Federal Rules of Civil Procedure?

Mr. ENGELBERG. You have to hang around long enough to make the motion, Senator. To borrow Nancy Buc's phrase about "process patent roulette," if you are the defendant in one of these cases, in order to claim that a charge was frivolous and was made with undue investigation, you have to have better facts than the party that made the charge.

Senator MATHIAS. Yes, but under the 1983 amendments, the attorney who files the case has to certify, quote, "that to the best of his knowledge, information and belief, formed after reasonable inquiry, it is well-grounded in fact and not interposed for any improper purpose."

Mr. ENGELBERG. I understand that, Senator, but someone has to make the motion that there has been a violation of rule 11. And if I as a defendant in a process patent case cannot instantly verify when I am handed the complaint that there is or is not infringement, I have to presume whether it is true or not that there is infringement in order to protect my business and get out of that product without ever gettng to the merits.

And that is the problem here.

Senator MATHIAS. Well, of course, rule 11 answers—was it Ms. Buc who talked about the retailers recovering cost—because under rule 11, the standards are enforceable by sanctions against the lawyer or against his client, and that would include costs.

Ms. BUC. I do not think that is quite what I had in mind, Senator.

Senator MATHIAS. But it is there.

Ms. BUC. But it is not enough. Al Engelberg is right. We are not making the charge here that most of these cases will be in bad faith. Our problem is that even if they are made in good faith, they are a disaster for retailers, and we are not the right people to bring them against.

If we are in a situation where the charge is made in bad faith, not something that we want to impute lightly or at all to the people who are bringing the cases, then you have to defend the case enough to find out that you can bring a rule 11 motion. It is not enough just for the plaintiff to lose the case to bring a rule 11 motion; you have to have some real bad faith there. That is not what we are imputing, and it is not much of a solace. I have not been in practice that long, but I have never seen a rule 11 motion, and I do not know that the 1983 changes are going to make that much difference. Most lawyers are not in bad faith. And this is bad litigation even if it is in good faith.

Senator MATHIAS. What about the other point that is sometimes made, that retailers are already protected against liability by contractual "hold harmless" clauses, by provisions in the Uniform Commercial Code which imply that there is a warranty against patent infringement.

Don't these mechanisms provide some protection?

Ms. BUC. I have drafted several of those, and they are nice, and you put them in there when you are the buyer to try to protect yourself against the seller. But in real life, most of them do not protect you unless you defend the litigation so that you have a basis for bringing litigation back against your supplier.

And to say that if you can stay and fight and win this litigation, and then you will have a terrific cause of action against the supplier, is not the kind of consolation that the average retailer wants. If I tell him that he has a good lawsuit, and then he will be able to sue his supplier, then he has got to pay me twice; he will not be happy.

Mr. ENGELBERG. Senator, there is an anomaly here, because the proponents say that they have to sue the customers rather than the foreign manufacturers, because they will never be able to collect damages. They turn around and say, "We can get an indemnity from the same people, and have them make good on it." Now, one or the other of those statements cannot be correct. And I think it leads to another question which really has not been addressed to any great degree, and that is how real is this question of not being able to get jurisdiction over foreign manufacturers.

The laws on long arm have been loosening and loosening and loosening up. There is a recently reported patent case in which a U.S. subsidiary of a foreign manufacturer was held to be enough of a presence here under "doing business" standards to establish a jurisdiction for infringement. We are not talking about not enforcing these patents. We are talking about a balanced approach which does not give one side or the other too much leverage. And the people who have the rights, if they have to struggle a little bit to enforce them by trying long arm and by using ITC procedures, or

some fair filters so that people who cannot defend themselves have an opportunity to develop a defense without having a damage claim hanging over their heads, that is too far in one direction, and I think that is really the problem we are facing here.

Senator MATHIAS. What about a retailer, whether it is one of Ms. Buc's drugstores or otherwise, is that retailer generally the importer, or is there a middleman somewhere?

Ms. BUC. It varies enormously. It depends on the product, it depends on the part of the world, it depends on the retailer. It can be either.

Senator MATHIAS. Well, if the retailer is the importer, which you say is the case sometimes——

Ms. BUC. Sometimes.

Senator MATHIAS [continuing]. How would the patentee get jurisdiction over the foreign manufacturer in order to fight the real party?

Ms. BUC. Well, I keep asking myself the same question that Mr. Engelberg just raised—why is not the presence of the goods in the United States enough of a start on long arm jurisdiction, and why not explore that approach first? That is what the ITC is, in effect, is a way to go after the goods in rem, rather than the "somebody" who happens to be holding them. That approach, it seems to me, is worth exploration.

Senator MATHIAS. To what extent do the contracts require the overseas supplier to submit to the jurisdiction? Is that a normal provision in these contracts?

Mr. ENGELBERG. Not to my knowledge, Senator.

Ms. BUC. Not to my knowledge.

Senator MATHIAS. Could it be?

Ms. BUC. I do not know.

Senator MATHIAS. You just have no experience with that?

Mr. ENGELBERG. To my knowledge, it is not used. I do not think in a typical supply contract, I have ever seen anything like that.

Senator MATHIAS. Well, getting back to my Shakespearean actor for a moment, Mr. Ginsburg this morning said that the scrupulous retailer has some obligation to inquire into the process used to make the product. Do you disagree with the Assistant Attorney General?

Ms. BUC. I do, I do. I think that what has to be recognized here is that the retailer has 12,000 products; that every one of them is the subject potentially not only of other kinds of patents, process patents, and the Food, Drug and Cosmetic Act, and the Wool Act, and everything imaginable; but there are a lot of things that a retailer needs the products to comply with. It does not take any unscrupulosity to be simply unable to do that downstream. The one who knows whether the process patent is violated is the one who made the goods. The one who knows whether the Food, Drug and Cosmetic Act is violated is the one who made the goods. And to expect realistically that a retailer is a logical downstream policeman is to expect the impossible.

Mr. ENGELBERG. Senator, one other point. There seems to be an assumption here that everybody always knows that there are patents and there is infringement. There are 4.5 million issued patents at this point. Companies like IBM and GE or the pharmaceutical

companies, if you do a search in the Patent Office on a defined technology, have hundreds if not thousands of patents. There is no provision anywhere, in this law or any other law, that requires a manufacturer to announce to the world in some way that "these are the processes I use to make my product, and they are covered by these patents," so that you would know, going into a business, that there is something specific you ought to look at.

I mean, we should not go off believing that all of the infringement cases that arise in the course of a year are willful and deliberate situations, particularly in the area of process patents.

Mr. HADDAD. Senator, in our case, which is different than the retailing case, and it has very practical immediate consequences, this legislation would, because of its complexity, dry up our raw supply of materials to make these finished goods. And the question we ask is where is that ITC case where ITC failed, and the patent holder was aggrieved? Where has the process fallen down? It has not. They did not have the cases last year, they do not have the cases this year. Maybe you just ought to exclude this industry from it. I do not know what goes on with Sony televisions or other things. But in the pharmaceutical industry, they do not have the cases. ITC is working well. We do not like the ITC, but it is working well, and why should we subject ourselves to the potential of drying up the source of raw materials when there is no factual base for that argument—and to drag us into arguments about T-shirts or Sony's or something else, I think is what I call the "flag-waving" over the real thing, which is really to keep us out of the market, which they have not been able to do competitively.

Senator MATHIAS. Well, now, as you hear, those bells are at me again, but let me just ask one last quick question before I put my jogging shoes back on.

What about an alternative? Suppose we simply added damages to the ITC process. You say you can live with the process as it is—you do not like it, but you are willing to live with it?

Mr. HADDAD. We can live with it, yes.

Senator MATHIAS. Suppose we added damages to it.

Mr. ENGELBERG. Well, I am not sure I understand the question, Senator. There is an Exclusion Order issued when there is a finding that that there is infringement, and in fact, if there is a failure of cooperation by the foreign manufacturer, there is precedent for an early finding of an adverse inference, and a potentially earlier issuance of an Exclusion Order. It seems to me that, consistent with what we are saying, there should not be any damages until there has been a prima facie case of infringement established, either by a court finding or by default, because the foreign manufacturer failed to come in and defend. And that would be true whether you are talking about ITC, district court, or anything else.

Mr. HADDAD. But Senator, are you asking a legal question or a political question, because I think once something is adjudicated, and the inference is that if damages are on the horizon, there will be less chance of infringement, and you are saying that this bill will go away as far as pharmaceutical manufacturing is concerned; then damages would be something to consider in the political context, you know, at some point in the process in exchange for.

Senator MATHIAS. Well, I was not offering a compromise——

Mr. HADDAD. No, I just wanted to see where it is coming from, because—you know, we have the law and the law is the law—but nobody wants to protect an infringer; there is too much at stake.

Senator MATHIAS. Well, I regret that we have been so repeatedly interrupted here. I appreciate your testimony very much, but because I feel a little sense of incompleteness about it, I am going to ask you to do as I have asked the other witnesses, to respond to questions which may be propounded as a result of this colloquy so far.

Mr. HADDAD. What is our timetable, Senator? There is some indication that they may stick this on the trade bill. I mean, do we have time to go through the process——

Senator MATHIAS. Well, as far as I am concerned, I cannot control what 99 other Senators do if the bill comes along, but that is not my scheme.

Mr. HADDAD. Thank you.

Senator MATHIAS. Thank you very much.

Mr. ENGELBERG. Thank you, Senator.

Senator MATHIAS. Now, we have one more panel. Let me ask Professor Fryer and Mr. Smegal, have they survived?

Mr. SMEGAL. Yes, Senator.

Professor FRYER. Yes.

Senator MATHIAS. Would you like to wait to deliver your statements after I vote, or would you rather just submit for the record?

Mr. SMEGAL. I am prepared to wait, Senator. I have come in from San Francisco, and I am delighted to be here, and I intend to stay, if you are willing, Senator.

Senator MATHIAS. OK. I will come back, and we will take care of it.

[Short recess.]

Senator MATHIAS. The committee will come to order.

Our last witnesses today will be Prof. William Fryer, of the University of Baltimore School of Law, and Mr. Thomas F. Smegal, Jr., president of the American Intellectual Property Law Association.

Gentlemen?

STATEMENT OF A PANEL, CONSISTING OF PROF. WILLIAM T. FRYER III, UNIVERSITY OF BALTIMORE SCHOOL OF LAW, BALTIMORE, MD, AND THOMAS F. SMEGAL, JR., PRESIDENT, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, ARLINGTON, VA

Professor FRYER. My name is William T. Fryer III, and I am from the University of Baltimore School of Law. It is a pleasure being here, and my written statement has been presented.

I think my role has been throughout this hearing to analyze the subject critically and to raise questions that should be discussed. I do not represent any of the other parties speaking at this hearing.

I have three topics which I raised in my paper, and I will only spend a few moments on one of them, in view of the time, and that one is the burden of proof shifting to the defendant, creating a presumption of liability.

The presumption issue seems to me the most critical problem, and I think we have to admit that the legislative history, and your

introductory remarks when the bill was presented, raise a very strong impression that there is such a presumption, even if it is not written in the bill. This fact is the reason for my concern.

My position is that a special rule on presumption could be very unfair to sellers and users who would be charged with infringement under the proposed law. My recommendation is that there be no special rule and the normal rule that the patent owner has the burden to prove its case should be followed.

I do have comments on four other points that were mentioned during the hearing today. They are on both sides of this debate.

My first comment is on the premature expiration of the product patent. It was mentioned by the biotech person, Mr. Ostro. Many of the product patents expire early, before significant commercialization. I urge your subcommittee to recognize this fact and the importance of protection on an improved process and the product it produces. It is an extremely important point and it should be emphasized time and again.

My second comment is that there is a need for a return on investment for the improved process patent owner. This owner needs the capital to continue its research. It needs the damages from infringement for the return on investment. The ITC proceeding does not provide these damages, only an injunction.

My third comment is that I questioned the drugstore owners' position that they cannot handle such problem of locating products on their shelves that infringe a patent. They said there is no time to check out these items, nor can they handle them through legal counsel. I submit they have to check the quality of these drugs. They certainly would sell nothing that has poor quality. Therefore, I submit this infringement problem is like the quality checks that they are continually monitoring with the manufacturer. They want to protect themselves both ways.

The last comment that I want to make is on the notice that must be given to the retailer that there is a patent infringement, in order for damages to be received. This notice includes the specific patent involved. Damages only occur after the notice is reviewed. The seller does not have to fish around and search the Patent and Trademark Office files, or go through 4 million patents to find out when a patent is being infringed. It pays damages, if there is infringement, only after being so notified.

Since I have just a few seconds left, I will end my comments with a suggestion on a very important point concerning the seller's and user's liability. I do think that you can sharpen up the present language in the proposed bill to make it clear exactly when the seller's and user's liability occurs. It is a little bit mushy now, even if it follows current patent law, but it is coming along. The language is an improvement from the earlier Senate bill S. 1535, 98th Congress, 1st session. My paper goes into more detail on this point.

Thank you.

Senator MATHIAS. Thank you very much, Professor.

[Professor Fryer's submissions for the record follow:]

PREPARED STATEMENT OF WILLIAM T. FRYER III

My name is William T. Fryer III, and I am a full-time law professor at the University of Baltimore School of Law in Baltimore, Maryland, where I have taught since 1980. Prior to 1980, I taught at the University of South Dakota School of Law, as a visiting professor at Pepperdine University Law School, and as an adjunct professor at Capital University School of Law in Columbus, Ohio. At each of these schools, except Pepperdine, I have taught antitrust and patent law courses and performed research in these fields and I continue to teach courses in these subjects at the Univeristy of Baltimore. I am an experienced patent attorney, having been a patent examiner, government attorney, corporate patent attorney and chief patent counsel, and law firm attorney. My active practice experience spans over 20 years, and thereafter I have served as a consultant and expert witness on several occasions. I give you this detailed introduction to show that I have a very broad and continuing interest as a teacher in the economic impact of the patent laws.

I am not speaking on behalf of any of the parties involved in this legislation. I was solicited by the Subcommittee staff to present my independent, critical analysis of the economic factors involved in this legislation and to offer my opinion on its impact. I will have a few specific recommendations for your consideration that should help bring the impact of this legislation into acceptable balance.

The ecomonic situation surrounding this legislation is best illustrated by a simple picture of Figure 1 on the next page. The subject is protection of products made by a process, referred to in this paper as process-product. Other processes for creating the product are not the subject of this legislation. These other processes are freely utilized, unless they are subject of U.S. patent protection. As matters now stand, the outward flow of U.S. technology for use in foreign countries creates products that are imported into the U.S. These imports help to cause an unfavorable balance of payments between the U.S. and other countries. While the latest technological developments in this outward flow of technology are usually protected by U.S. product and process patents, helping U.S. industry recover some of its investment, the product patents usually expire earlier, as they are the first patents obtained. The improved processes create the same product in a cheaper and more efficient way, sometimes making the product manufacturing costs finally low enough for wide commercial availability of the product.

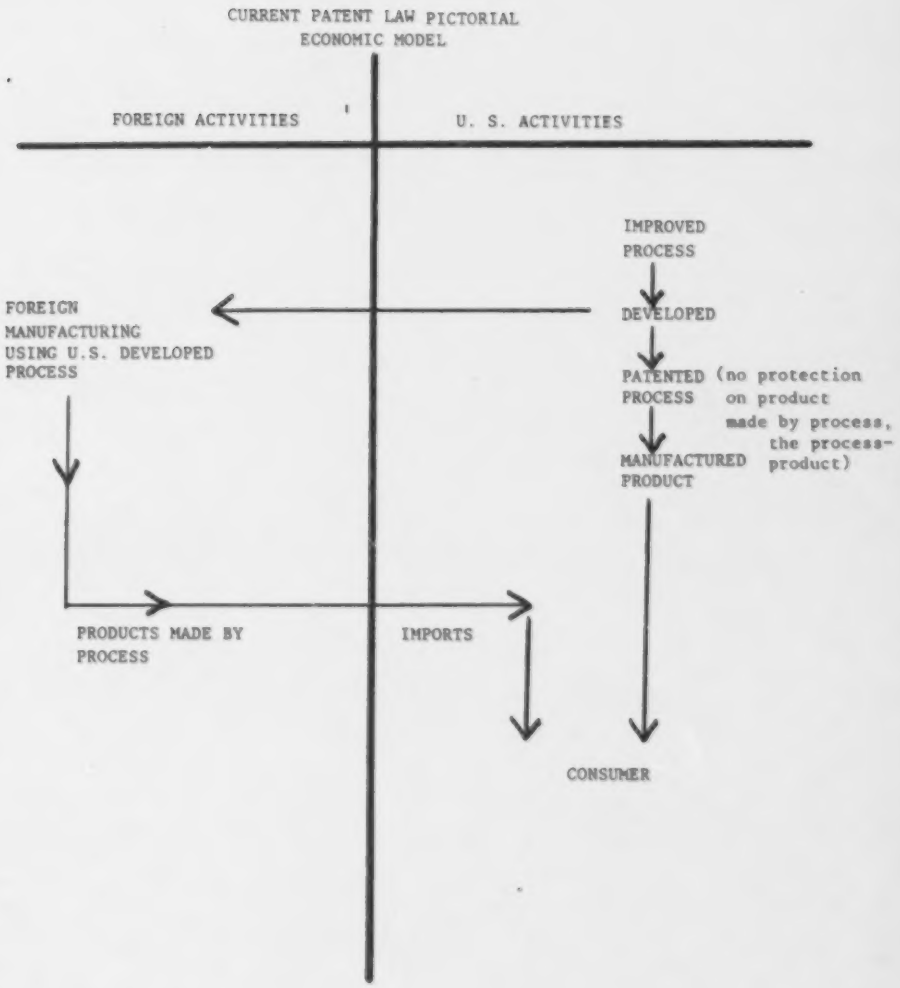
At the present time, these improved U.S. developed processes are being used overseas and the resultant products imported into the U.S. without any U.S. patent protection for the products created by these improved processes. U.S. patent law does not allow protection of a product made by a patented process unless there is a separate patent on the product. Since the product patent usually expires first, the improved process creator is not able to stop importation of the product created by that improved process, even though its technology is being used to create products that compete with its own products in the U.S.

Competition from imports helps to give the U.S. consumer the highest product quality for the lowest price. Many U.S. and foreign companies are dependent on this unprotected technology and the U.S economic system recognizes this industry as a necessary part of the global competitive system. These industries wait for U.S. patents to expire and provide valuable competition with these patent owners. They challenge invalid patents and remove these undesired obstacles to the free flow of technology.

The U.S. patent system fits into this economic picture by increasing the incentive to create and manufacture new products and processes. Since tremendous investment is needed for new technology development, the absence of a reasonable return on that investment will discourage U.S. industry from creating new process-products. While these economic principles are well accepted, the application to the specific situation for this legislation requires a careful study of the economic impact. For this legislation to be effective it must create the needed investment incentive while not interfering with the necessary utilization of unpatented technology to maintain the competitive process.

55-522 O - 86 - 6

FIGURE 1



With these facts and basic economic relations in hand, the stage is set to analyze the difficult question of whether S 1543, or a suitable amendment thereof, will benefit the U.S. economy. If this legislation becomes law it will stop the use of the patented process and the sale and use of processproducts in the U.S. A significant U.S. and foreign industry based on the use of this patented process technology will have to discontinue sales in the U.S. until the process patent expires. It will have to rely on unpatented technology to make the product. The cost of the process-product to the consumer for a limited period of time may be higher than if the technology was freely available for use overseas and importation and sale in the U.S. On the other hand, the process-product will have to be priced to encourage wide use for an adequate return on investment, tending to keep the price down. The same product made by processes that are freely available for use will be in competition, creating an even greater pressure on price of the process-product. After P's limited period of product-process patent protection, the process and its product is available for use by all, and the price will be determined by the competitive system.

The U.S. process patent owner does have a procedure now for preventing imports of process-products, through the Internaltion Trade Commission (ITC). This procedure is much less important than the enforcement of the patent law in the federal courts, because the ITC can grant only an injunction, while the federal court can grant an injunction and assess damages. The patent law allows damages for a period of six years prior to the date of infringement suit. The ITC procedure is relative fast and has resulted in significant enforcement of U.S. process patents to stop process-product importation. While the ITC procedure offers an opportunity for the process patent owner to enforce its rights, there are negative aspects too. The ITC review is run on such a tight schedule, its enforcement effectiveness must be questioned. Another concern is the ITC staff controls the review process, a factor that leaves the outcome of a case in doubt, and in the end the procedure is a political decision. The President has the right to deny any order of the ITC, and it is always hard to tell what the White House advisors, and other administration officials will recommend to the President.

The federal court system enforcement of the patent rights added by S 1543 would not suffer from the same problems encountered with the ITC. The question that should be put to the proponents of this legislation is whether they would give up the present ITC procedure for process-product injunctive protection, if the patent laws were amended to add process-product protection. The willingness to make this exchange would support their argument that the present ITC system is inadequate in many respects. This change would focus the dispute in one arena and satisfy to some extent those who consider the patent process-product law amendment only serves to complicate the legal process and give the patent owner too much opportunity to obstruct the flow of technology.

A second problem area created by this legislation is the burden placed on the defendant in the enforcement of a process-product patent in a federal court. Prior proposals for process-product protection have created a presumption that the patent process was being used when some level of proof was reached by the patent owner. Then the defendant had to come forward with proof that the process used was not the patented one. This disclosure, ultimately by the manufacturer, could force it to reveal its trade secrets. Whether the manufacturer is in the U.S. or overseas the problem is the same. Recent refusal by the Coke Cola Company to reveal its trade secret formula to a federal court is an example of an extreme situation, but it is a real problem for anyone with a trade secret. I see no reason to have a special presumption on burden of proof in process-product litigation. The courts have established rules of civil procedure and evidence to protect a manufacturer's secrets and require the patent owner to prove its case, and they should apply to all patent litigation. If the patent owner cannot find the evidence, it should not prevail.

My suggestion is to ask the industry representatives sponsoring this bill if they will accept in S 1543 a statement that the burden of proof used in other patent infringement litigation will be followed. If they agree to this point, a lot of the possible anti-competitive impact from this legislation is removed. Then, there is no supportable argument that this legislation is specifically designed or can be used unfairly to draw out the secrets of manufacturers, or to put retailers or wholesalers in the position of forcing the disclosure of the manufactuer's secrets to do business in the U.S. My understanding is that it is harder to prove a process is made a particular product, but companies under laws in other countries similar to the one proposed here have been able to meet that burden effectively. They should be willing to accept the same responsibility under the U.S. patent system.

The final area of economic impact that I will consider is the effect of this legislation on the U.S. industry component that sells or uses products made by a process-product patent under S 1543. These industry components will have to be concerned now over whether they are patent infringers and must stop selling or using the process-product and pay damages for past infringement. Under present U.S. patent law, only the manufacturer in the U.S. is liable, as the one who uses the patented process, since the process-product is not protected, without a separate product patent. The proposed legislation that protects also the process-product when the process is protected could dampen economic activity, unless it is clear how the sellers, users, and manufacturers can operate with adequate notice that there is patent infringement.

In general the infringement notice provision under U.S. patent law is rather liberal. Damages for a product infringement start when actual notice is received by an infringer, or before when a patent notice is placed on the product. It is clear from S 1543 that there is no liability for damages due to notice on the process-product, and liability for damages starts when an infringer knows, or is notified of the infringement. There is a vague statement in the legislation about the effect of an infringement suit. This language needs to be clarified. Apparently, it means when an infringement suit is filed against a person, the damage period begins for that person.

The impact of the S 1543 damage provision on sellers and users, with liability going back to some informal communications of possible patent infringement, leaves the situation too unsettled for the economic system to function effectively. There are several simple ways to clear up this point, such as using the procedures now incorporated in H.R. 1900, the Industrial Design Protection Act of 1985. Another approach is to use the procedure found in the Semiconductor Chip Protection Act of 1984. I prefer the industrial design bill provision that in essence does not hold the sellers liable unless they know of the infringement and refuse to reveal the manufacturer of the goods, or if they are in collusion with the manufacturer in knowingly manufacturing and selling, or using, an infringing product. This method of concentrating on the root of the infringement problem, the manufacturer and its partners, avoids the scare tactics that can disrupt necessary competitive activity. I also favor written, registered or certified mail notice of infringement, before the seller or user is liable for damages prior to being sued.

In summary, I have presented three suggestions: (1) elimate the ITC action in favor of relying entirely on the federal court patent suit for protection of the patented process-product, (2) the use of the same burden of proof for all patent litigation, including process-product suits, and (3) clarification of who is liable and when. With these changes this legislation will effectively serve the U.S. economy. While I have focused on areas needing change, I want to emphasize that this legislation is needed to stimulate the U.S. economy. I am convinced from my experience and research that the U.S. industrial investment, jobs, and the consumer will all benefit by this change.

I have carefully studied the criticisms of this type of legislation presented in the previous hearings on S 1535 and S 1841, on April 3, 1984. You have noted that I accept with qualification some of these criticisms and offer simple solutions. Some of the prior objections were based on technical arguments that the U.S law should not be changed, because there is no working requirements here, as in some other countries, or there are limitations in 35 U.S.C. §102 concerning the geographic effect of prior art. As I understand these arguments, they are misguided and do not recognize the fundamental point that our patent system is carefully designed to serve the U.S ecomony. The courts, Congress, and practitioners recognize that in an capitalistic society useful technology will be developed and utilized. It has been so in the past and it is true now. This legislation is not for the purpose of restructuring the basic principles of the U.S. patent system. Our attention should be directed and energy spent on how to fine tune a change in the U.S. patent system, where a clear need has been demonstrated. I trust my comments are useful in the further consideration of this important legislation. I welcome questions at any time and if I can be of further assistance, please let me know.

Summary

1. An analysis of the ecomonic situation surrounding S 1543 is presented.

2. Recommendations for improvement in this legislation are in the areas of eliminating the ITC action available now to obtain an injunction on a patented process-product in favor of relying solely on the federal court action with the added right to prevent use or sale of the process-product; clarification of the burden of proof for the defendant in a patent infringement suit; and clarification of when a seller or user of a process-product is liable as an infringer.

3. This legislation is very important to the U.S. economy and in effective form it should be enacted promptly.

UNIVERSITY OF BALTIMORE • SCHOOL OF LAW
1420 North Charles Street • Baltimore, Maryland 21201
301-625-3170

October 29, 1985

Senator McC Mathias, Jr.
Russell Building
U.S. Capitol
Washington, D.C. 20510

Subject: Supplemental Comments on S 1543 (99th Congress, 1st Session) - The Process Patent Amendment of 1985

Dear Senator Mathias:

In further response to the question you asked me at the hearing on the subject bill, I would like to draw to your attention a problem created by a formal or implied presumption in S 1543 on the burden of proof that will shift at some point and time in a law suit. You asked me whether the problem of finding an infringer who sells a product made by a patented process is a different situation, warranting a special rule on the burden of proof.

I liked your story about the unfortunate actor, so I will wind up my analysis using that example, but first I must review some basic infringement situations. Consider the situation where a process patent owner sues an alleged infringer in the U.S. under present U.S. patent law. The burden is on the patent owner to prove infringement. Any attempt to discover the process used by the alleged infringer will be subject to the federal rules and the discretion of the court. If an alleged infringer's secret manufacturing process is needed for a comparison with the patented process, the court will attempt to keep the process secret and not destroy its value, while allowing access to it for purposes of the law suit. A case-by-case approach would be used to handle this sensitive problem. The casebook on patent law that I use has the U.S. Supreme Court decision if E.I. DuPont deNemours Powder Co. vs. Masland, 244 U.S. 100 (1917), copy enclosed, to illustrate this delicate problem.

Clearly suits based on a process patent could be misused in an attempt to reveal a competitor's secrets, but there are legal ethic and court supervision standards that should minimize the problem. The patent owner still has to convince a jury or judge by a preponderance of the evidence that there is infringement.

S 1543 does not change the burden of proof on process patent infringement, i.e., infringement by the manufacturer using the patented process. This legislation does affect the burden of proof and liability of the seller and user for the product made by a patented process (I use the coined term "process-product" for this item.) I am not convinced yet that a special rule on burden of proof should apply under the proposed legislation, when the process owner sues those who sell or use a process- product. A U.S. company allegedly infringing the process patent will be subject to the burden of proof mentioned above for process patent infringement. On the other hand, a user or seller of the process-product will be liable under S 1543 once some presumptive level of proof is shown, less than the level required for a manufacturer infringer under existing patent law. The only way for the seller or user to avoid liability in this situation is to

have the manufacturer come forward with the evidence on its process, to show a non-infringing process is being used.

My question is whether this predicament for the seller and user is fair to them. They lose, not the manufacturer, if the manufacturer does not come forward with the evidence. Of course, the manufacturer looses the customer's business, but in the end would a manufacturer come forward to reveal its secrets to save one customer?

To use the example that you gave, of the actor with the bad lines, it seems he would get the boos, rotten eggs, and now civil liability for his role, in using the writer's script. I am not sure the writer will come on stage under these circumstances, and that is what we are asking the analogous manufacturer to do. To complicate the sellers situation even more, it is clear that the burden-shifting rule will affect the importers primarily. The U.S. manufacturers will be subject to the usual rules of discovery and access to the needed manufacturing information, under control of the court. The actor analogy will mean that the writer will have to travel from a usually safe harbor overseas, to the U.S. courts, a threatening stage for the foreign manufacturer. While our sympathy should not lie with the foreign manufacturer, it does mean that the user or seller who is a U.S. company, generally, will be left in an uncertain position if the foreign manufacturer does not want to cooperate.

In summary, your question can be answered by a simple "yes", the situation for proof of process-product infringement is different. It exposes the seller in an expensive and complexed legal conflict between the patent owner and foreign manufacturers. It would help the patent owner to have this burden-shifting rule, but it makes the seller the pawn and the possible victim of the "process".

As I said at the hearing, I think it is the burden of the sponsors for this legislation to prove that the present burden of proof rule will not work for them in the process-product infringement situation. The facts are out there, but they are not in the legislative record yet, from the experience in other countries with a system like S 1543, where there is no shift in the burden of proof. I have heard discussions that indicate they win a significant number of these suits. If these comments are true, there is no need to have such a rule in the U.S. My suggestion is to "shift the burden" to the sponsoring organizations to make the case for this change, so the record clearly demonstrates a need. Then, I would support the special burden rule if the records shows it is essential for an effective operation of our patent system, with a safety net for the sellers and users, as explained below.

In the patent law and corporation law courses I teach, there are cases where a burden of proof presumption is used. In these cases, usually, the defendant has a fiduciary duty, such as in a corporation to its shareholders, or the party has the best knowledge of the facts. I am enclosing a copy of a typical corporate duty case, Sinclair Oil Corp. vs. Levien, 280 A. 2d 717 (S.Ct. Del. 1971), with relevant parts marked.

The patent law example is illustrated in the enclosed Hycor Corp. case, 222 USPQ 553 (CAFC 1984). The patent owner has the initial burden of proof to show infringement. Once the defendant, the alleged infringer, presents evidence to create a presumption that the patent is invalid, due to a statutory bar, the burden shifts to the patent owner to overcome the presumption of invalidity. The reason for this burden shift is that the patent owner has the best knowledge of the facts on the statutory bar. This burden on the patent owner, or in the case of a corporation with a fiduciary duty, is proper, but it is not the same situation as a seller or user in the middle of a process-product infringement suit. The seller or user does not have such a fiduciary duty to the patent owner, and is not in

possession of the knowledge essential to determining whether there is infringement. In the latter case, admittedly, there is indirect access to that knowledge, by the seller or user exercising persuasion, or contract obligations, with the manufacturer to obtain the needed evidence. The question remains whether it is fair to put the seller or user in that position.

The critical issue is "fairness", to both the seller, users, and the process patent owner. It is a difficult decision on where to draw the line. My suggestion is that if the burden presumption is kept, the seller and user should be given several safety nets. One proposal, as a minimum, would be to clarify when infringement occurs, requiring written notice of infringement by a certified or registered mail. I would consider adding another protection for the seller or user that would start damage liability only after a law suit is filed and notice thereon is given to the seller or user, so that damages do not start until the suit is filed. This delay in the normal beginning of damages, which occurs when notice of infringement is received, before any suit is filed, would give the seller less financial exposure. The filing of a suit is evidence of a serious legal dispute and puts everyone on notice. The use of threats are mere notice of infringement to the seller or user, to coerce sellers or users would be less. A third approach would be to set damages to begin after a decision by the trial court that there is infringement, or when there is a shift in the burden of proof to the seller to prove that there was not infringement. This longer delay in damage initiation favors the seller and could encourage protracted litigation. I would not recommend either of the last mentioned compromises.

My role as a law professor in the review of this legislation has been to analyze the issues and facts and call the situation as I see it. I offer my views on the economic impact of this legislation with the final comment that I strongly support this kind of legislation. I trust my further comments are helpful.

Sincerely yours,

W. T. Fryer III

William T. Fryer III
Professor

WTF:pn

Enclosure: Sinclair Oil Corp. case, 280 A.2d. 717
Hycor Corp. case, 222 USPQ 553
E.I. Dupont deNermours case, 244 U.S. 100

280 A.2d 717 (1971) Page 717

SINCLAIR OIL CORPORATION, Defendant Below, Appellant,

v.

Francis S. LEVIEN, Plaintiff Below, Appellee.

Supreme Court of Delaware,

June 18, 1971.

WOLCOTT, C. J., CAREY, J., and CHRISTIE, Judge, sitting.

WOLCOTT, Chief Justice.

This is an appeal by the defendant, Sinclair Oil Corporation (hereafter Sinclair), from an order of the Court of Chancery, 261 A.2d 911 in a derivative action requiring Sinclair to account for damages sustained by its subsidiary, Sinclair Venezuelan Oil Company (hereafter Sinven), organized by Sinclair for the purpose of operating in Venezuela, as a result of dividends paid by Sinven, the denial to Sinven of industrial development, and a breach of contract between Sinclair's wholly-owned subsidiary, Sinclair International Oil Company, and Sinven.

Sinclair, operating primarily as a holding company, is in the business of exploring for oil and of producing and marketing crude oil and oil products. At all times relevant to this litigation, it owned about 97% of Sinven's stock. The plaintiff owns about 3000 of 120,000 publicly held shares of Sinven. Sinven, incorporated in 1922, has been engaged in petroleum operations primarily in Venezuela and since 1959 has operated exclusively in Venezuela.

Sinclair nominates all members of Sinven's board of directors. The Chancellor found as a fact that the directors were not independent of Sinclair. Almost without exception, they were officers, directors, or employees of corporations in the Sinclair complex. By reason of Sinclair's domination, it is clear that Sinclair owed Sinven a fiduciary duty. Getty Oil Company v. Skelly Oil Co., 267 A.2d 883 (Del.Supr. 1970); Cottrell v. Pawcatuck Co., 35 Del. Ch. 309, 116 A.2d 787 (1955). Sinclair concedes this.

The Chancellor held that because of Sinclair's fiduciary duty and its control over Sinven, its relationship with Sinven must meet the test of intrinsic fairness. The

standard of intrinsic fairness involves both a high degree of fairness and a shift in the burden of proof. Under this standard the burden is on Sinclair to prove, subject to careful judicial scrutiny, that its transactions with Sinven were objectively fair. Guth v. Loft, Inc., 23 Del.Ch. 255, 5 A.2d 503 (1939); Sterling v. Mayflower Hotel Corp., 33 Del.Ch. 293, 93 A.2d 107, 38 A. L.R.2d 425 (Del.Supr.1952); Getty Oil Co. v. Skelly Oil Co., supra.

[1] Sinclair argues that the transactions between it and Sinven should be tested, not by the test of intrinsic fairness with the accompanying shift of the burden of proof, but by the business judgment rule under which a court will not interfere with the judgment of a board of directors unless there is a showing of gross and palpable overreaching. Meyerson v. El Paso Natural Gas Co., 246 A.2d 789 (Del.Ch. 1967). A board of directors enjoys a presumption of sound business judgment, and its decisions will not be disturbed if they can be attributed to any rational business purpose. A court under such circumstances will not substitute its own notions of what is or is not sound business judgment.

[2] We think, however, that Sinclair's argument in this respect is misconceived. When the situation involves a parent and a subsidiary, with the parent controlling the transaction and fixing the terms, the test of intrinsic fairness, with its resulting shifting of the burden of proof, is applied. Sterling v. Mayflower Hotel Corp., supra; David J. Greene & Co. v. Dunhill International, Inc., 249 A.2d 427 (Del.Ch.1968); Bastian v. Bourns, Inc., 256 A.2d 680 (Del.Ch.1969) aff'd. Per Curiam (unreported) (Del.Supr.1970). The basic situation for the application of the rule is the one in which the parent has received a benefit to the exclusion and at the expense of the subsidiary.

Recently, this court dealt with the question of fairness in parent-subsidiary dealings in Getty Oil Co. v. Skelly Oil Co., supra. In that case, both parent and subsidiary were in the business of refining and marketing crude oil and crude oil products. The Oil Import Board ruled that the subsidiary, because it was controlled by the parent, was no longer entitled to a separate allocation of imported crude oil. The subsidiary then contended that it had a right to share the quota of crude oil allotted to the parent. We ruled that the business judgment standard should be applied to determine this contention. Although the subsidiary suffered a loss through the administration of the oil import quotas, the parent gained nothing. The parent's quota was derived solely from its own past use. The past use of the subsidiary did not cause an increase in the parent's quota. Nor did the parent usurp a quota of the subsidiary. Since the parent received nothing from the subsidiary to the exclusion of the minority stockholders of the subsidiary, there was no self-dealing. Therefore, the business judgment standard was properly applied.

[3–5] A parent does indeed owe a fiduciary duty to its subsidiary when there are parent-subsidiary dealings. However, this alone will not evoke the intrinsic fairness standard. This standard will be applied only when the fiduciary duty is accompanied by self-dealing—the situation when a parent is on both sides of a transaction with its subsidiary. Self-dealing occurs when the parent, by virtue of its domination of the subsidiary, causes the subsidiary to act in such a way that the parent receives something from the subsidiary to the exclusion of, and detriment to, the minority stockholders of the subsidiary.

We turn now to the facts. The plaintiff argues that, from 1960 through 1966, Sinclair caused Sinven to pay out such excessive dividends that the industrial development of Sinven was effectively prevented, and it became in reality a corporation in dissolution.

From 1960 through 1966, Sinven paid out $108,000,000 in dividends ($38,000,000

in excess of Sinven's earnings during the same period). The Chancellor held that Sinclair caused these dividends to be paid during a period when it had a need for large amounts of cash. Although the dividends paid exceeded earnings, the plaintiff concedes that the payments were made in compliance with 8 Del.C. § 170, authorizing payment of dividends out of surplus or net profits. However, the plaintiff attacks these dividends on the ground that they resulted from an improper motive—Sinclair's need for cash. The Chancellor, applying the intrinsic fairness standard, held that Sinclair did not sustain its burden of proving that these dividends were intrinsically fair to the minority stockholders of Sinven.

[6] Since it is admitted that the dividends were paid in strict compliance with 8 Del.C. § 170, the alleged excessiveness of the payments alone would not state a cause of action. Nevertheless, compliance with the applicable statute may not, under all circumstances, justify all dividend payments. If a plaintiff can meet his burden of proving that a dividend cannot be grounded on any reasonable business objective, then the courts can and will interfere with the board's decision to pay the dividend.

Sinclair contends that it is improper to apply the intrinsic fairness standard to dividend payments even when the board which voted for the dividends is completely dominated. In support of this contention, Sinclair relies heavily on American District Telegraph Co. [ADT] v. Grinnell Corp., (N.Y.Sup.Ct.1969) aff'd. 33 A.D.2d 769, 306 N.Y.S.2d 209 (1969). Plaintiffs were minority stockholders of ADT, a subsidiary of Grinnell. The plaintiffs alleged that Grinnell, realizing that it would soon have to sell its ADT stock because of a pending anti-trust action, caused ADT to pay excessive dividends. Because the dividend payments conformed with applicable statutory law, and the plaintiffs could not prove an abuse of discretion, the court ruled that the complaint did not state a cause of action. Other decisions seem to support Sinclair's contention. In Metropolitan Casualty Ins. Co. v. First State Bank of Temple, 54 S.W.2d 358 (Tex.Civ.App.1932), rev'd. on other grounds, 79 S.W.2d 835 (Sup.Ct. 1935), the court held that a majority of interested directors does not void a declaration of dividends because all directors, by necessity, are interested in and benefited by a dividend declaration. See, also, Schwartz v. Kahn, 183 Misc. 252, 50 N.Y.S. 2d 931 (1944); Weinberger v. Quinn, 264 A.D. 405, 35 N.Y.S.2d 567 (1942).

[7] We do not accept the argument that the intrinsic fairness test can never be applied to a dividend declaration by a dominated board, although a dividend declaration by a dominated board will not inevitably demand the application of the intrinsic fairness standard. Moskowitz v. Bantrell, 41 Del.Ch. 177, 190 A.2d 749 (Del.Supr. 1963). If such a dividend is in essence self-dealing by the parent, then the intrinsic fairness standard is the proper standard. For example, suppose a parent dominates a subsidiary and its board of directors. The subsidiary has outstanding two classes of stock, X and Y. Class X is owned by the parent and Class Y is owned by minority stockholders of the subsidiary. If the subsidiary, at the direction of the parent, declares a dividend on its Class X stock only, this might well be self-dealing by the parent. It would be receiving something from the subsidiary to the exclusion of and detrimental to its minority stockholders. This self-dealing, coupled with the parent's fiduciary duty, would make intrinsic fairness the proper standard by which to evaluate the dividend payments.

[8] Consequently it must be determined whether the dividend payments by Sinven were, in essence, self-dealing by Sinclair. The dividends resulted in great sums of money being transferred from Sinven to Sinclair. However, a proportionate share of this money was received by the minority shareholders of Sinven. Sinclair received nothing from Sinven to the exclusion of its

minority stockholders. As such, these dividends were not self-dealing. We hold therefore that the Chancellor erred in applying the intrinsic fairness test as to these dividend payments. The business judgment standard should have been applied.

[9] We conclude that the facts demonstrate that the dividend payments complied with the business judgment standard and with 8 Del.C. § 170. The motives for causing the declaration of dividends are immaterial unless the plaintiff can show that the dividend payments resulted from improper motives and amounted to waste. The plaintiff contends only that the dividend payments drained Sinven of cash to such an extent that it was prevented from expanding.

The plaintiff proved no business opportunities which came to Sinven independently and which Sinclair either took to itself or denied to Sinven. As a matter of fact, with two minor exceptions which resulted in losses, all of Sinven's operations have been conducted in Venezuela, and Sinclair had a policy of exploiting its oil properties located in different countries by subsidiaries located in the particular countries.

From 1960 to 1966 Sinclair purchased or developed oil fields in Alaska, Canada, Paraguay, and other places around the world. The plaintiff contends that these were all opportunities which could have been taken by Sinven. The Chancellor concluded that Sinclair had not proved that its denial of expansion opportunities to Sinven was intrinsically fair. He based this conclusion on the following findings of fact. Sinclair made no real effort to expand Sinven. The excessive dividends paid by Sinven resulted in so great a cash drain as to effectively deny to Sinven any ability to expand. During this same period Sinclair actively pursued a company-wide policy of developing through its subsidiaries new sources of revenue, but Sinven was not permitted to participate and was confined in its activities to Venezuela.

[10] However, the plaintiff could point to no opportunities which came to Sinven. Therefore, Sinclair usurped no business opportunity belonging to Sinven. Since Sinclair received nothing from Sinven to the exclusion of and detriment to Sinven's minority stockholders, there was no self-dealing. Therefore, business judgment is the proper standard by which to evaluate Sinclair's expansion policies.

[11] Since there is no proof of self-dealing on the part of Sinclair, it follows that the expansion policy of Sinclair and the methods used to achieve the desired result must, as far as Sinclair's treatment of Sinven is concerned, be tested by the standards of the business judgment rule. Accordingly, Sinclair's decision, absent fraud or gross overreaching, to achieve expansion through the medium of its subsidiaries, other than Sinven, must be upheld.

Even if Sinclair was wrong in developing these opportunities as it did, the question arises, with which subsidiaries should these opportunities have been shared? No evidence indicates a unique need or ability of Sinven to develop these opportunities. The decision of which subsidiaries would be used to implement Sinclair's expansion policy was one of business judgment with which a court will not interfere absent a showing of gross and palpable overreaching. Meyerson v. El Paso Natural Gas Co., 246 A.2d 789 (Del.Ch.1967). No such showing has been made here.

Next, Sinclair argues that the Chancellor committed error when he held it liable to Sinven for breach of contract.

In 1961 Sinclair created Sinclair International Oil Company (hereafter International), a wholly owned subsidiary used for the purpose of coordinating all of Sinclair's foreign operations. All crude purchases by Sinclair were made thereafter through International.

On September 28, 1961, Sinclair caused Sinven to contract with International whereby Sinven agreed to sell all of its

crude oil and refined products to International at specified prices. The contract provided for minimum and maximum quantities and prices. The plaintiff contends that Sinclair caused this contract to be breached in two respects. Although the contract called for payment on receipt, International's payments lagged as much as 30 days after receipt. Also, the contract required International to purchase at least a fixed minimum amount of crude and refined products from Sinven. International did not comply with this requirement.

Clearly, Sinclair's act of contracting with its dominated subsidiary was self-dealing. Under the contract Sinclair received the products produced by Sinven, and of course the minority shareholders of Sinven were not able to share in the receipt of these products. If the contract was breached, then Sinclair received these products to the detriment of Sinven's minority shareholders. We agree with the Chancellor's finding that the contract was breached by Sinclair, both as to the time of payments and the amounts purchased.

Although a parent need not bind itself by a contract with its dominated subsidiary, Sinclair chose to operate in this manner. As Sinclair has received the benefits of this contract, so must it comply with the contractual duties.

[12] Under the intrinsic fairness standard, Sinclair must prove that its causing Sinven not to enforce the contract was intrinsically fair to the minority shareholders of Sinven. Sinclair has failed to meet this burden. Late payments were clearly breaches for which Sinven should have sought and received adequate damages. As to the quantities purchased, Sinclair argues that it purchased all the products produced by Sinven. This, however, does not satisfy the standard of intrinsic fairness. Sinclair has failed to prove that Sinven could not possibly have produced or someway have obtained the contract minimums. As such, Sinclair must account on this claim.

Finally, Sinclair argues that the Chancellor committed error in refusing to allow it a credit or setoff of all benefits provided by it to Sinven with respect to all the alleged damages. The Chancellor held that setoff should be allowed on specific transactions, e. g., benefits to Sinven under the contract with International, but denied an over all setoff against all damages claimed. We agree with the Chancellor, although the point may well be moot in view of our holding that Sinclair is not required to account for the alleged excessiveness of the dividend payments.

We will therefore reverse that part of the Chancellor's order that requires Sinclair to account to Sinven for damages sustained as a result of dividends paid between 1960 and 1966, and by reason of the denial to Sinven of expansion during that period. We will affirm the remaining portion of that order and remand the cause for further proceedings.

See p.557

222 USPQ 553 (1984) Page 553

Court of Appeals, Federal Circuit

Hycor Corporation v. The Schlueter Company

No. 83-935

Decided July 2, 1984

Before Baldwin and Miller, Circuit Judges, and Kellam, Senior District Judge.*

Baldwin, Circuit Judge.

This appeal is from the February 25, 1983 judgment of the United States District Court for the Western District of Wisconsin,[1] sitting without a jury, holding appellant Hycor Corporation's (Hycor) U.S. Patent No. 3,876,548 ('548), issued April 8, 1975, entitled "Screening Method and Apparatus," invalid under 35 USC 103 for obviousness and 35 USC 102(b) for being on sale and in public use more than one year prior to the filing date of the application for the subject patent. The trial court also held the patent invalid because it found that the patentee, Welles, and his patent counsel breached their duty of candor to the Patent and Trademark Office (PTO) by failing to cite relevant prior art and failing to disclose the uses and sales of Rotostrainers[2] made more than one year prior to the filing date of the application. Further, the court held the lack of candor amounted to fraud in the PTO. Attorney fees were awarded to appellee, The Schlueter Company (Schlueter), pursuant to 35 USC 285. The trial court did not reach the issue of infringement. Hycor appeals from the invalidity determination and the attorney fees award.

We *affirm* the trial court's decision invalidating claims 1-9 of the '548 patent on the basis that the claimed invention was in public use more than one year prior to the filing date of the application. We *reverse* the trial court's decision to award attorney fees.

---

* The Honorable Richard B. Kellam, Senior District Judge, United States District Court, Eastern District of Virginia, sitting by designation.

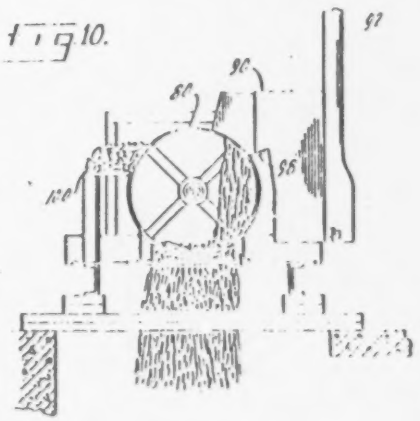
[1] 564 F.Supp. 996, 219 USPQ 651 (1983).

[2] The Rotostrainer is the device which embodies the invention of the '548 patent.

Background

Hycor owns the '548 patent which issued to Donald P. Welles, Jr., the president of Hycor.

The '548 patent describes and claims an apparatus for separating solids from liquids such as waste water. The apparatus incorporating the claimed invention is self-cleaning, and is more fully described below. Figs. 10, 12, and 13 of the patent are here reproduced.



Included in the device are a headbox 90 (Fig. 10) which receives the mixture to be separated via a pipe 92. A cylindrical screen 80 is positioned adjacent to the headbox, extending the length of the headbox; the screen rotates slowly via a motor. The mixture in the headbox is deposited onto the screen so that, as the screen turns, liquid falls through the screen while the solids are carried onto a platform 100. A wiper (doctor blade) 98 has an edge bearing against the surface of the screen which cleans the exterior of the screen as it rotates. The free-falling liquid which passes through the interior of the screen cleans the screen as it passes through the screen bottom.

The screen is made up of parallel bars (Figs. 12,13) that have a wedge-shaped cross

section. The bars are attached to a support structure so that they are perpendicular to the axis of the screen. An important feature of the invention is the particular geometry and configuration of bars or wires[1] having inwardly diverging sides and which are closely spaced to form the screen exterior or screening medium. As described in the patent:

> The angle (a) is formed by the inwardly-tapering sides 146 and a line generally parpendicular to the outer surface W, should be greater than about 7° and less than 45°. It has been determined that when this angle is less than about 7°, there tends to be a packing of solid spongy material which has passed through the outer openings between bars. On the other hand, when the angle is greater than about 7°, the spongy material does not pack, but tends to be forced by the water through the screen, leaving free unblinded openings for the filtering and screening of the liquid-solid mixture. If the angle becomes too great, i.e., above about 45°, the screen itself is sufficiently weakened because of the cross sectional shape of the bars, that the unit has a tendency to have reduced life. Accordingly, these limits are important and screens formed with bar relationships outside of these limits will not satisfactorily perform their intended purpose.

Also important is the relationship between the diameter of the screen and the thickness of the bars (H) (Fig. 12).

> In like manner, the relationship of the diameter of the screen and the ratio of screen diameter to the thickness of each of the bars 142 or the distance H is important. It has been determined that the ratio of screen diameter to H must be greater than about 75 in order to have a sufficiently large screen to provide the cascading free fall of water to self-clean the spaces between the bars as the screen rotates.

All nine of the '548 patent's claims are in issue. Claims 1-3, paragraphing by us, are illustrative:

> 1. In a device for separating and dewatering the generally spongy solids from the liquid in sanitary sewage, food processing, meat packing and the like, including
>
> a cylindrical screen having a screening medium about its outer periphery made up of spaced circumferentially arranged, generally parallel bars surrounding a generally open interior,
>
> means supporting the screening medium for rotation about a generally horizontal axis so that the surface of the screening medium is rising on one side and descending on the other,
>
> means for rotating the screening medium,
>
> a headbox containing a liquid-solid medium to be separated directly adjacent the surface of the screening medium and opening against the rising side thereof above a horizontal plane through its axis,
>
> a solids discharge adjacent the outer surface of the screening medium and spaced from the headbox in the direction of its rotation and beyond a vertical plane through its axis,
>
> movement of the screening medium carrying the separated solids from the headbox toward the solids discharge with the majority of the liquid passing through the screening medium at the headbox and falling freely in a cascading column down to the bottom area of the screening medium toward the inner surface of the medium primarily in an area on the rising side below the horizontal plane through its axis, the bars that make up the screening medium each having a generally flat outer face which, as a group, make up a cylidrical, generally smooth exterior surface with limited openings between adjacent bars to effect maximum separation adjacent the headbox followed by transportation of the separated solids to the solids discharge, the bars having inwardly diverging sides which define upwardly opening cleaning troughs at the bottom of the cascading column,
>
> the side of one bar defining an included angle with the opposed side of an adjacent bar greater than about 14° and less than about 90°, with ratio of screen diameter to radial bar thickness being no less than about 75.
>
> 2. The structrure of claim 1 further characterized in that the included angle between the opposed sides of adjacent bars is on the order of 26°.
>
> 3. The structure of claim 1 futher characterized in that the separation of the bars is on the order of 0.060 inches.

The patent application for Welles '548, Serial No. 435,163, was filed with the PTO on January 21, 1974 as a continuation-in-part application because it contained new subject matter that was not previously disclosed or claimed in two prior Welles applica-

[1] Throughout this opinion the terms "wires" or "bars" are used interchangeably to refer to the structural elements of the screening itself, as distinguished from the transverse rods that form the supports of the screen.

tions. The application also contained new Figs. 12 and 13 which showed the profiles of the wedge wires and descriptions of the figures. Fig. 12 was taken directly from the 1967 catalog entitled, "Screen Products for Industry," published and distributed by the Johnson Screen Division of Universal Oil Products (Johnson catalog), discussed more extensively below.

The examiner initially rejected all the claims of Serial No. 435,163, and Welles and his patent attorneys were granted a personal interview with the examiner. Welles then responded to the outstanding first office action by amending his claims. In the amendment Welles agreed that U.S. Patent No. 2,294,179 to Hawley (Hawley teaches the general rotary strainer structure and that U.S. Patent No. 828,715 to Cook (Cook '715) teaches wedge wire in a cylindrical strainer, but argued that none of the prior art overcame the blinding (clogging) problem by use of only a rotary screen having wedge wire within a critical range of values.

Welles also submitted an affidavit which disclosed 1972 test data relating to the alleged success of the newly introduced and claimed configuration for wedge-shaped screen wire. The affidavit suggested that wedge wire having a radial height of 0.100 inches and an exterior face width of 0.060 inches and an included angle of 26 degrees (Johnson No. 60 wire)[4] was most successful in preventing clogging of the screen. In a side-by-side test, one Rotostrainer using a Johnson No. 60 wire screen cylinder (within the scope of the claims) and the other Rotostrainer using a Johnson No. 69 wire screen cylinder (outside the scope of the claims) were compared. The Rotostrainer having No. 69 wire lost 35-40% of its original capacity to filter material, while the Rotostrainer having No. 60 wire had not changed its capacity to filter material. In the affidavit, Hycor did not reveal that its source of wire screen cylinders was Johnson, but did mention a "source." The claims were allowed as amended.

Issues on Appeal

1. Whether the trial court erred in holding the patent in suit invalid.

2. Whether the trial court abused its discretion in awarding attorney fees under 35 USC 285.

Opinion

Validity

Hycor appeals from the trial court's judgment that the '548 patent is invalid under 35 USC 102(b) for being both on sale and in public use more than one year before the filing of the subject application and 35 USC 103 for obviousness. Since the public use of the claimed invention more than one year before the filing date of the subject application is dispositive of the issue of validity, we find it necessary to discuss only this issue in affirming the trial court's decision on validity.

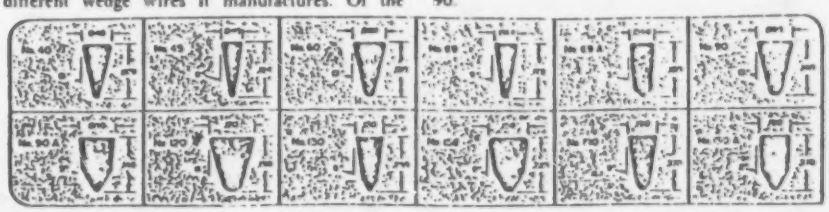
I.

The use of three Hycor Rotostrainers using Johnson No. 60 wire screen cylinders in a sewage treatment plant and in two meat packing plants in 1972 and up to January 21, 1973, the critical date, is the basis for the public use issue under 35 USC 102(b).

The trial court found that in 1972, Hycor provided two Rotostrainers to the North Chicago Sewage Treatment Plant, one using a screen cylinder with a diameter greater than 11 inches and having a Johnson No. 60 wedge wire screen and the other using a Johnson No. 69 wedge wire screen cylinder. The strainers remained at the plant until 1974. Yet, the trial court found and Welles admitted that no more than four to five days of testing was required to determine the effectiveness of Hycor's Rotostrainer in a commercial setting. No secrecy was imposed on any of the employees at the plant regarding use or testing.

The trial court also found that Hycor displayed photographs of the Rotostrainers at

[4] The Johnson catalog has a pictorial representation (below) of the surface profiles of the twelve different wedge wires it manufactures. Of the twelve configurations, the trial court found Welles experimented with three: No. 60, No. 69, and No. 90.



the North Chicago plant to representatives of Oscar Mayer & Co. and Packer Land Packing Co. in 1972 as part of Hycor's efforts to sell Rotostrainers.

The trial court found side by side testing of Rotostrainers had taken place at North Chicago in 1972, despite the fact that Welles testified that such testing did not occur until the spring of 1973 and that any testing in 1972 was by observation only. The 1972 tests were not documented or otherwise recorded by Welles. The court based its finding that testing took place in 1972 on the Welles affidavit submitted to the PTO, which said in part, "In 1972 we obtained and tested a unit like in Figures 9-14 with a number of screens or cylinders in two groups." The result of the controlled tests was that the Rotostrainer with a Johnson No. 60 wire screen cylinder significantly outperformed the one with a Johnson No. 69 wire screen cylinder. The court reasoned that Welles' memory was likely more precise in October, 1974, when he executed the affidavit, than when he testified in 1982. Also, Welles' affidavit was consistent with a January 10, 1973 letter to the South St. Paul Sewage Treatment Plant in which Welles wrote:

> Our findings at North Chicago roughly confirm your findings at St. Paul on the #69 profile wire in that we appear to get some blinding over time in sanitary sewage, whereas with the #60 profile wire we were able to run 40 days without any change in flow rate and without cleaning.

The trial court was unpersuaded by Welles' contrary testimony that the North Chicago tests were not conducted until 1973 or that testing continued to the spring of 1973, past the critical date.

The trial court also found that in the summer of 1972 Hycor sent two Rotostrainers to Iowa Beef Processors, one of which used a Johnson No. 60 wire screen cylinder, and one of which used a Johnson No. 69 wire screen cylinder. Also, in November, 1972, Hycor provided E. Kahn & Sons a Rotostrainer using a Johnson No. 60 wire screen cylinder for a 15-day pilot test with an eye toward Kahn's purchase of the apparatus. Welles testified the cylinder came apart in two days.

The trial court found that Hycor commercially exploited the invention in using the Rotostrainer: "The 1972 and early 1973 use of plaintiff's Rotostrainer by sewage treatment plants and food processors was intended to develop commercial demand for the Rotostrainer and to exploit its commercial value."

Hycor points to several errors of the trial court. Hycor argues that the burden was on Schlueter to establish a prima facie case of public use of the complete invention and that Hycor therefor should not have been required to show that the purpose of the uses was exclusively experimental. Hycor further argues the court improperly assessed the evidence of the various uses Hycor made of its Rotostrainers. Hycor contends the court should have found all the uses of the Rotostrainers experimental because, according to the Welles affidavit, successful testing was not completed until after the critical date.

II.

[1] This court has considered the public use bar under section 102(b)[1] before. TP Laboratories, Inc. v Professional Positioners, Inc., 724 F.2d 965, 220 USPQ 577 (Fed. Cir. 1984). We said in TP Laboratories that there is no separate "experimental use" exception, but rather, a single issue: Was there public use under section 102(b)? Id. at 971, 220 USPQ at 582. The issue must be determined by cohsidering the totality of circumstances. Factors to be considered in deciding whether there is a public use include, for example, the length of the test period, whether any payment has been made for the device, whether there is a secrecy obligation on the part of the user, whether progress records were kept, whether persons other than the inventor conducted the asserted experiments, how many tests were conducted, and how long the testing period was in relationship to tests of other similar devices. Id. at 971-72, 220 USPQ at 582.

Once a prima facie case of public use before the critical date has been made, the patent owner must come forward with clear and convincing evidence to counter that showing. TP Laboratories, 724 F.2d at 971, 720 USPQ at 582; In re Dybel, 524 F.2d 1393, 1401, 187 USPQ 593, 598 (CCPA 1975); In re Blaisdell, 242 F.2d 779, 784, 113 USPQ 289, 292-93 (CCPA 1957). Facts underlying the conclusion of public use are subject to the clearly erroneous standard.

[2] The trial court's conclusion that there was public use of the claimed invention rests on its findings that Hycor, prior to the critical

---

[1] 35 USC 102(b) provides in pertinent part:
A person shall be entitled to a patent unless —

* * *

(b) the invention was * * * in public use * * * in this country, more than one year prior to the date of the application for patent in the United States.

date, had commercially exploited the Rotostrainers having Johnson No. 60 wire screen cylinder, and had successfully demonstrated that the NO. 60 wire screen cylinder outperformed the No. 69 wire screen cylinder.[6]

Photographs, taken by Welles and Hycor's vice president for marketing, of the Rotostrainers at the North Chicago plant were shown to representatives of prospective customers such as Oscar Mayer & Co. and Packer Land Packing Co. in order to obtain a sale. The record also discloses that no confidentiality obligations were imposed on any employees of the facilities which were using the Rotostrainer. The Rotostrainer was advertised and promoted in 1972 and sales literature was circulated freely. On cross-examination, Welles admitted that he had told Packer Land that the Rotostrainer had been successfully tested at Iowa Beef and Oscar Mayer in the hope of generating a sale.[7] Nor was Welles able to point to any significant documentary evidence of testing.

The trial court evaluated the character of the uses of the North Chicago sewage treatment plant and the food processing and packing plants after reviewing the testimonial and documentary evidence. We are unable to say that the trial court's findings which underlie its conclusion are clearly erroneous. We conclude the record adequately supports those findings.

In view of this evidence, we also cannot agree with Hycor that Schlueter failed to establish a prima facie case of public use of the complete invention. Indeed, there is clear and convincing evidence of such barring use.

Hycor argues here that Welles had not successfully completed testing of a Rotostrainer using a No. 60 wire screen cylinder during 1972. While there might be some ambiguity as to the meaning of the Welles affidavit submitted to the PTO ("in 1972 we obtained and tested"), the trial court concluded that Welles completed testing of the claimed invention in 1972. The January 10, 1973 letter to South St. Paul Sewage Treatment Plant is also ambiguous as to whether further experimental testing was to be undertaken.[8] Nevertheless, the trial court considered all the evidence relating to the uses and tests of the Rotostrainer with a No. 60 wire screen cylinder, the surrounding commercial activity, the testimony of Welles, and the affidavit submitted to the PTO. We conclude that the trial court's finding that Hycor successfully tested the Rotostrainer in 1972 was not clearly erroneous.

Finally Hycor argues that the trial court improperly shifted the burden of proof by requiring it to show by clear and convincing evidence the exclusively experimental nature of its public use of Rotostrainers embodying the claimed invention in 1972 and early 1973. We disagree.

[3] It is well settled that under 35 USC 282 the ultimate burden of persuasion of patent invalidity rests solely with the party attacking validity. This court in American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 USPQ 763, 771 (Fed. Cir. 1984) said:

---

[6] Neither the testing of an invention on the commercial premises of another nor the fact that the owner of such premises, the inventor, or the public benefit from such testing alone create a public use bar. City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126, 134-35 (1877).

[7] The following is an excerpt from Welles' cross examination testimony at trial:

Q. [Exhibit] 157 indicates that the unit has been successfully tested at Iowa Beef Processors and Oscar Mayer; is that correct?
A. That's what it says.
Q. And that was true at the time?
A. Yes. It was successful.
Q. And those tests were completed at that time, isn't that correct?
A. I'm not saying they were completed. They were assumed to be successful as far as the customer was concerned. They were not successful as far as I was concerned.
Q. You don't indicate in 157 that they weren't successful as far as you're concerned, do you?
A. No. But that wouldn't be my prerogative.
Q. You indicated they were successful in the hope of generating a sale; isn't that correct?
A. Yes.

[8] The January 10, 1973 letter, quoted earlier, continues:

Test results thus far indicate that we should rapidly move back to the #60 wire to provide a faster breakaway for the water to drop through the cylinder and the solids to wash out. We are currently estimating that tooling and the production of two cylinders for the unit now at South St. Paul would run in excess of $10,000, assuming total feasibility, and deliveries would run from 10 to 12 weeks. Needless to day, [sic] we will want to give a lot of thought to this prior to moving ahead with the #60 wire in 28-5/8" diameter.

Your verbal outline of the testing program over the next two weeks sounds excellent, Keith, and I would very much like to be there myself when we change over to the sanitary sometime within the next three weeks, if this is contemplated.

The further testing referred to in the second quoted paragraph may, of course, indicate further testing of the feasibility of No. 60 wire in the South St. Paul facility.

> §282 creates a presumption that a patent is valid and imposes the burden of proving invalidity on the attacker. That burden is constant and never changes. * * *

See also TP Laboratories, 724 F.2d at 971, 220 USPQ at 582; Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579, 219 USPQ 8, 11-12 (Fed. Cir. 1983). The standard of proof of facts necessary to support a legal conclusion of invalidity is "clear and convincing." Railroad Dynamics, Inc. v. A. Stucki Company, 727 F.2d 1506, 1516, 220 USPQ 929, 938 (Fed. Cir. 1984); American Hoist, 725 F.2d at 1360, 220 USPQ at 770.

The trial court did not shift to Hycor the burden of proving the validity of the '548 patent. Instead, the trial court correctly imposed on Hycor the burden of going forward with convincing evidence to counter Schlueter's prima facie showing of invalidating public use. As this court said in TP Laboratories, 724 F.2d at 971, 220 USPQ at 582:

> Thus, the court should * * * [look] at all of the evidence put forth by both parties and should * * * [decide] whether the entirety of the evidence led to the conclusion that there had been "public use." This does not mean, of course, that the challenger has the burden of proving that the use is not experimental. Nor does it mean that the patent owner is relieved of explanation. It means that if a prima facie case is made of public use, *the patent owner must come forward with convincing evidence to counter that showing.* [Emphasis added.]

Hycor failed to convincingly counter Schlueter's showing. Indeed, Schlueter has met its burden of "proving facts necessary to a conclusion of invalidity." TP Laboratories, 724 F.2d at 971, 220 USPQ at 582 (quoting Richdel, Inc. v. Sunspool Corp., 714 F.2d at 1579, 219 USPQ at 11-12).

The trial court considered the totality of circumstances. Hycor failed to put forward convincing evidence negating the public use and failed to convince us of clear error in the trial court's findings. We therefore hold that the court correctly held the claimed invention was in public use under section 102(b).

Attorney Fees

The trial court awarded attorney fees to Schlueter on the basis that Hycor was guilty of "extraordinary misconduct," based on its conclusion that Welles and his patent counsel committed fraud in the PTO. Another reason for the award was that the court found Welles commenced suit even though Welles "had good reason to know that [the '548 patent] was probably invalid and, therefore, not subject to infringement."

The trial court made the following findings of fact relating to lack of candor and fraud in the PTO.

> The Johnson catalog teaches the identical geometric configurations for a continuously helically wound wedge-shaped screen wire as called for in the claims of Welles '548, and the self-cleaning characteristics which are imparted by a cylindrical screen manufactured from wedge wire which serves to minimize the blinding or clogging of screen openings. From reading the Johnson catalog, a prospective customer would learn that Johnson screen products are designed for use in waste water treatment installations, in the food processing industry, and in other "dewatering" or straining applications. Also the customer would learn that the Johnson screens employed a continuous slot, or wedge wire, construction, rather than a round-hole or mesh design; that the wedge wire design decreased clogging or "blinding"; that the wedge wire configuration was adaptable to any outside to inside flow of liquid or to a reverse flow from inside to outside; and that the screens could be used in a rotating situation as well as in a fixed position.
>
> Further, as an aid to the customer in choosing the most effective surface profile and support rod spacing for the particular installation, the Johnson catalog featured a chart plotting the relationship of spatial opening between adjacent wires to the open area on the screen surface. The chart shows that, at a spacing of .060 inches, the use of no. 60 wire will result in 50% of the screen's surface being open, while use of no. 69 wire with the same spacing will reduce the open area to about 47-48%. The catalog shows twelve different configurations of wedge wire, two of which have included angles of 26 degrees or greater (the No. 60 and the No. 90) and two of which show included angles of 18 degrees (the No. 69 and the No. 190). In reality, the included angle of the No. 69 wire is about 14 degrees; the 9 degree one-sided angle shown in the catalog is erroneous. * * *
>
> The catalog shows that Johnson screens could be fabricated as flat panels of any shape, or in conical or cylindrical shapes; it shows also that Johnson screens have been used as centrifuge baskets and as vertical spin driers.
>
> Welles never advised the Patent Office of the Johnson catalog.

Regarding intent, the trial court found:

> [F]raud can be inferred from the failure of Welles or his patent counsel to cite the Johnson catalog or to advise the patent office of the source of the wedge wire screens (or the source of the drawings used for figure 12 of the continuation-in-part application).

With regard to Hycor's various public use and on sale activities the trial court found:

> Plaintiff knew or should have known of the high degree of relevance of the Johnson catalog and its own on-sale activities as prior art. When plaintiff filed this lawsuit, it was aware of the possible invalidity of its patent and of the legal consequences of asserting such a patent.

The trial court concluded that:

> Welles and his patent counsel did breach their duty of candor to the patent office; that the information withheld (the Johnson catalog and the 1972 and early 1973 installations and sale of the No. 60 Rotostrainer) would have been considered important by a competent patent examiner in deciding whether to issue a patent on the Rotostrainer; and that Welles's breach of his affirmative duty to bring the withheld information to the attention of the examiner destroys any presumption of validity to which the patent would otherwise be entitled and renders the Welles '548 patent unenforceable.

In another section of the opinion, the trial court separately concluded, "Welles's failure to cite the Johnson catalog and the public use of the Rotostrainer prior to January 21, 1973, was material and intentional and constitutes fraud on the patent office, rendering invalid the Welles '548 patent."

[4] An applicant for a patent is under a duty of candor in dealing with the PTO. One of our predecessor courts analyzed the relationship of trust that must exist between the PTO and those wishing to receive patent protection for inventions. The court said, "[t]he highest standards of honesty and candor on the part of applicants in presenting such facts to the office are thus necessary elements in a working patent system. We would go so far to say they are essential." Norton v. Curtiss, 433 F.2d 779, 794, 167 USPQ 532, 544 (CCPA 1970).

A breach of the duty of candor owed to the PTO, that prevents the grant of a patent or causes it to be held invalid or unenforceable, occurs when material information is misrepresented or withheld, and such misrepresentation or withholding is intentional or accompanied by gross negligence or bad faith. Our review of the trial court's findings of fact and conclusions of law focuses on whether this case presents exceptional circumstances under 35 USC 285. That is, did Welles and his patent counsel by breaching their duty of candor to the PTO by fraud, bad faith, or gross negligence, meet the "exceptional" case requirement.

Fraud must be proved by clear and convincing evidence. Orthopedic Equipment Co. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983), Norton, 433 F.2d at 797, 167 USPQ at 546-47; See Miller, Fraud on the PTO, 58 JPOS 271 (1976). Further, "an applicant's misrepresentation or failure to meet his 'duty to disclose to the Office information * * * which is material' will not in itself render a patent invalid or unenforceable, see 37 CFR 1.56(a) and (d)," American Hoist, 725 F.2d at 1364, 220 USPQ at 774.

A finding of fraud may be determined only by a careful balancing of intent in light of materiality. As this court recently said in American Hoist:

> Questions of "materiality" and "culpability" are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established, whereas a greater showing of the materiality of withheld information would necessarily create an inference that its non-disclosure was "wrongful."

725 F.2d at 1363, 220 USPQ at 773 (citing Digital Equipment Corp. v. Diamond, 653 F.2d 701, 716, 210 USPQ 521, 538 (1st Cir. 1981)).

The trial court in this case tracked one of the several standards of materiality, PTO Rule 56(a),* in concluding that the failure of Welles and his patent counsel to disclose the Johnson catalog to the PTO was a breach of the duty of candor. The trial court determined that the Johnson catalog was the most relevant information for the examiner because the catalog disclosed the screen cylinders which Welles used in his comparative testing. It was with these tests that Welles showed that one screen cylinder significantly outperformed another screen cylinder. The court also said the examiner would have found highly relevant the fact that Welles only worked with two or three possibilities from a universe of the twelve Johnson wedge wire screen profiles shown in the catalog.

---

*[I]nformation is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent * * *. 37 CFR 1.56(a), third sentence (1983).

The trial court also looked to the "Remarks" submitted by Welles during prosecution. In the "Remarks" Welles said that the invention described by one piece of prior art (Hawley, U.S. Patent No. 2,294,179) would be unsatisfactory because the screening medium would clog immediately, and that the invention described by another piece of prior art (Cook, U.S. Patent No. 828,715) which had longitudinal wedges rather than circumferential wedges, would not allow effective cascading action. Welles did not contest the combinability of the references. . .

The trial court said that the affidavit's reference to Johnson as "our source" influenced the examiner's decision to allow the application, and that Hycor's argument that Johnson would not show which wedge wire configurations worked best was "disingenuous." The trial court further said that if Johnson had been cited, "the examiner would have realized not only that the wedge wire configuration used by Welles was prior art, but that it was obvious for Welles or anyone else to try more than one of the Johnson configurations to obtain a better cleaning effect than Hawley had been able to achieve."

The only relevant testimony of Welles on the question of materiality is that he supplied the catalog to counsel at the time the application was prepared, and that he did not know of any better reference to show the wedge wire shape. Since the only other evidence of whether the examiner would have considered the Johnson catalog important to his decision to allow the operation is the prosecution history,[9] we must look to it for guidance.

The prosecution history shows the examiner was aware that the screen cylinders were standard items and that the two Rotostrainers which were tested used two of these standard items which were very similar to each other in terms of included angles and radial dimensions. All nine of the claims substituted by amendment were allowed. Therefore, the trial court's findings on materiality are clearly erroneous. What is clear from the file history is that the examiner would not have considered the catalog important in light of the test results.

[5] Other information not disclosed to the PTO, which the trial court also concluded was material concerned the 1972 and early 1973 uses and sales of Rotostrainers using either No. 60 or No. 69 wire. The prosecution history is devoid, however, of any evidence of these uses other than the testing use recited in the Welles affidavit. We conclude that the trial court's finding, that these uses and sales would have been considered important to a reasonable examiner is not clearly erroneous, especially in view of our invalidity holding based on the public use of the Rotostrainer."

[6] We now turn our attention to the intent element which is a requisite in determining the existence of fraud. Norton, 433 F.2d at 795, 167 USPQ at 545. Direct evidence of wrongful intent is not required. As this court said in Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151, 219 USPQ 857, 861 (Fed. Cir. 1983): "The duty of candor owed the PTO being uncompromising, it would deal a deathblow to that duty if direct proof of wrongful intent were required." On the other hand, simple negligence, oversight, or an erroneous judgment made in good faith is not sufficient to satisfy the intent element. Aside from direct evidence of wrongful intent — i.e., deliberate scheming — intent may be proven by a showing of acts the natural consequences of which are presumably intended by the actor. Kansas Jack, Inc. v. Kuhn, 719 F.2d at 1151, 219 USPQ at 862, American Hoist, 725 F.2d at 1363, 220 USPQ at 773. The lower threshold for finding intent is therefore satisfied by evidence of gross negligence. Id. That threshold was not breached in the present case.

The trial court said, "there [cannot] be any question of Welles' intent to withhold the information from the patent office. The careful omission of any reference to Johnson and the misleading nature of the 'Remarks' submitted to the patent office allow no other conclusion." After reviewing the record, we conclude that the trial court's finding that the intent requisite to a conclusion of fraud could be inferred from failure to cite the Johnson catalog is clearly erroneous. The conclusion of the trial court that the withholding of the information in question was made through fraud is also erroneous as a matter of law because there is no support for it in the evidence of record.

On the issue of intent as to the pre-critical date uses, the trial court said failure to advise the PTO of the 1972 and early 1973 sales and installations of the Rotostrainer was deliberate since it was information peculiarly within Welles' knowledge. While we agree that the

---

[9] The examiner was neither called to testify at the trial nor deposed.

[10] Another related problem, not discussed, by the trial court, involves falsification of the inventor's oath. That oath, among other things, requires an applicant to state that he does not know of public uses or sales of the invention made more than a year prior to the application.

information about sales and installations should have been disclosed, see note 11 supra, failure to provide such information in this case amounts to an honest mistake in judgment insufficient to establish intent.

Although the actions of Welles and his patent counsel taken in the prosecution of the patent application that issued as the '548 patent should have been different, the evidence of record shows Welles and his counsel are guilty of no more than simple negligence or a good faith error of judgment. Because the requisite intent is lacking here, we hold there is no clear and convincing evidence of fraud on the part of Welles and his patent counsel.

[7] A finding of exceptional circumstances is required before a trial court can exercise its discretion to award reasonable attorney fees under 35 U.S.C. §285. Stevenson v. Sears, Roebuck & Co., 713 F.2d 705, 712-13, 218 USPQ 969, 975-76 (Fed Cir. 1983). An award of attorney fees is reviewed under the abuse of discretion standard, and an award must be set aside if it is unsupported by adequate findings of the basis for the award. Hughes v. Novi American, Inc., 724 F.2d 122, 124, 220 USPQ 707, 709 (Fed. Cir. 1984).

The trial court awarded attorney fees in this case because Welles committed fraud in the PTO and because when suit was commenced, Welles had good reason to know that the '548 patent was probably invalid. In view of our foregoing conclusion that there was no fraud in the PTO, and because there is no evidence in the record that Welles probably knew the '548 patent was invalid, the trial court's finding that this case is exceptional is clearly erroneous. The trial court therefore abused its discretion by awarding attorney fees to Schlueter, and accordingly, we reverse that portion of the trial court's decision.

Conclusion

The judgment of the trial court is affirmed with respect to 35 USC 102(b) invalidity, and is reversed with respect to the award of attorney fees.

Affirmed in Part, Reversed in Part

244 U.S. 100 (1917) Page 100

E. I. DU PONT DE NEMOURS POWDER COMPANY ET AL. *v.* MASLAND ET AL.

CERTIORARI TO THE CIRCUIT COURT OF APPEALS FOR THE THIRD CIRCUIT.

No. 210. Argued May 4, 1917.—Decided May 21, 1917.

MR. JUSTICE HOLMES delivered the opinion of the court.

This is a bill to prevent the defendant Walter E. Masland from using or disclosing secret processes the knowledge of which was acquired by the defendant while in the plaintiffs' employ. The defendant admits that he intends to manufacture artificial leather, to which some of the plaintiffs' alleged secret processes relate, but denies that he intends to use any inventions, trade secrets, or secret processes of the plaintiffs that he may have learned in any confidential relation, prefacing his denial, however, with the averment that many of the things claimed by the plaintiffs are well known to the trade. A preliminary injunction was refused at first. 216 Fed. Rep. 271. But before the final hearing the defendant proposed to employ one or more experts and to make such disclosures to them as the preparation of the defence might require. Thereupon the District Court issued a preliminary injunction against disclosing any of the plaintiffs' alleged processes to experts or witnesses during the taking of proofs, but excepting counsel, with leave to move to dissolve the injunction if occasion to consult experts arose. Later a motion to dissolve was denied and the hearing was continued for a decision by the Appellate Court. 222 Fed. Rep. 340. The Circuit Court of Appeals reversed the decree. 224 Fed. Rep. 689. Before any further order was entered the writ of certiorari was granted by this court.

The case has been considered as presenting a conflict between a right of property and a right to make a full

defence, and it is said that if the disclosure is forbidden to one who denies that there is a trade secret, the merits of his defence are adjudged against him before he has a chance to be heard or to prove his case. We approach the question somewhat differently. The word property as applied to trade-marks and trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence that he accepted. The property may be denied but the confidence cannot be. Therefore the starting point for the present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs, or one of them. These have given place to hostility, and the first thing to be made sure of is that the defendant shall not fraudulently abuse the trust reposed in him. It is the usual incident of confidential relations. If there is any disadvantage in the fact that he knew the plaintiffs' secrets he must take the burden with the good.

The injunction asked by the plaintiffs forbade only the disclosure of processes claimed by them, including the disclosure to experts or witnesses produced during the taking of proofs—but excepting the defendant's counsel. Some broader and ambiguous words that crept into the decree, seemingly by mistake, may be taken as stricken out and left on one side. This injunction would not prevent the defendant from directing questions that should bring out whatever public facts were nearest to the alleged secrets. Indeed it is hard to see why it does not leave the plaintiffs' rights somewhat illusory. No very clear ground as yet has been shown for going further. But the judge who tries the case will know the secrets, and if in his opinion and discretion it should be advisable and necessary to take in others, nothing will prevent his doing so. It will be understood that if, in the opinion of the trial judge, it is or should become necessary to reveal the secrets to others it will rest in the judge's discretion to determine whether, to whom, and under what precautions, the revelation should be made.

Decree reversed and case remanded for further proceedings in conformity with this opinion.

Senator MATHIAS. Mr. Smegal.

STATEMENT OF THOMAS F. SMEGAL, JR.

Mr. SMEGAL. Thank you very much, Senator Mathias.

I am Thomas F. Smegal, Jr., president of the American Intellectual Property Law Association which, as I am sure you are aware, is a national society of more than 5,000 of the 10,000 or so lawyers that specialize in intellectual property. Our membership includes lawyers from corporate, government practice, lawyers from private practice, such as myself, lawyers associated with universities, such as Dr. Fryer, small businesses and large businesses, lawyers active in both the domestic and international transfer of technology.

As a result of this diverse membership that we have, we come here with no particular bias or particular opinion. We are here to support and commend this subcommittee for its continuing efforts to correct a longstanding defect in the legal rights of process patent owners.

Under title 35, United States Code, section 101, there are four categories of protectable inventions. There are machines, there are manufactured products, and there are compositions of matter. In addition to that, there are processes. In each of those categories is also the subject of improvement patents.

The key in this whole matter is what section 271(a) provides. Now, this is one of the sections that would be amended by S. 1543. What 271(a) provides is that one who obtains a patent has the right to exclude others from making, using, and selling that invention.

With respect to a machine, it provides protection against someone else making the machine, using the machine, or selling the machine. The same rights are provided for a manufacturer, such as the products we have been hearing about this morning. Also, that same set of rights is provided for those who would have a patent on a composition of matter.

The thing that is lacking, the thing that prevents process patents from having full citizenship under the Patent Act, is that a process patent only has two of those rights. Under our present law, the process patentee has the right to exclude others from using the process or selling the process. He does not have the right to exclude others from making the process in the sense of the end result, what the process makes. And that is why we are here, and that is what this is all about.

The situation is clarified very simply by your legislation. It provides the other means of providing rights to the process patentee. We have heard a lot of testimony this morning by the prior panel with respect to the 12,000 products that are on the shelves of all these retailers out there at the corner drugstore. What they fail to state is that all of those 12,000 products are at the present time subject to possible allegation of patent infringement under any of the 4.5 million U.S. patents that now exist. The situation that would be presented were this legislation to become law is no different than what exists right now. If they are buying products from one of my clients without getting a "hold harmless," without getting an understanding from that manufacturer that that product they are buying is not the subject of an issued U.S. patent, if they

are not getting a "hold harmless," some understanding that if they are sued, they will be defended by the manufacturer, that situation is going to be no different under this process patent bill. They will still have the same kind of circumstances. They will still have the same number of products, which are subject to the same number of possible suits for product patent infringement or process patent infringement. The situation has not changed.

The issue of damages is a red herring. The law already provides that an innocent infringer is not subject to damages until such time as they are put on actual notice. We have section 287, which makes it very clear, and section 287 is carried over into this legislation; there is a provision for amending section 287. So that particular standard of damages is already there and nothing is changed. All you would be doing with this legislation is giving to the process patent owner the same kind of bundle of rights that the other categories of patent protection of inventions have always had under our patent laws.

They expressed a concern about the patentee, the process patentee, suing their manufacturer. Well, the problem with that is, they know who their manufacturer is. They have got a business relationship with this foreign manufacturer. The poor patentee that owns the process patent does not know who they are dealing with, and it is a much more difficult standard to apply for the process patentee to have to go and find their foreign manufacturer than it is to put the burden on them to tell their foreign manufacturer they are being sued, and to remind the foreign manufacturer that there is a provision in their purchase contract which says that the foreign manufacturer is going to stand in their shoes with respect to litigation. That is the simple way out of this. They have got easy contract language to do it. I do it all the time. "Seller agrees to hold buyer harmless from charges of patent infringement." It is as simple as that. It does not take much in their contract, and they have all got it in; they have got warranties now, Senator.

[Mr. Smegal's submissions for the record follow:]

PREPARED STATEMENT OF THOMAS F. SMEGAL, JR.
PRESIDENT, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

The American Intellectual Property Law Association (AIPLA) is a national society of more than 5000 lawyers engaged in the practice of patent, trademark, copyright, licensing, and related fields of law affecting intellectual property rights. AIPLA membership includes lawyers in private, corporate, and government practice; lawyers associated with universities, small business, and large business; and lawyers active in both the domestic and international transfer of technology.

We commend the Subcommittee for continuing to press forward the effort to correct a long standing defect in the legal rights of the process patent owners. In the last Congress, a measure nearly identical to S. 1543 was unanimously approved by the full Judiciary Committee but was not enacted into law. The AIPLA supports S. 1543 and supports the efforts of the Subcommittee to see that it is enacted in this Congress.

There are facts and impressive statistics know to the Members of this Subcommittee which demonstrate that U.S. technical superiority in the world is now threatened. We in AIPLA know from first-hand experience that competition in world markets in high technology products and goods produced by advanced technological methods and processes is growing stiffer for American business each year. This declining ability to compete is clearly having a serious impact on American exports and imports and is contributing to America's massive trade deficit.

Many U.S. patents cover processes for making a product. Under those patents, the patentee has the right to exclude others from using the patented process in the U.S. A

process patent owner can benefit from his invention by using it himself to make and sell a product or by licensing others to do so.

To evade the process patent owner's rights, unscrupulous persons may now use the protected process outside of the U.S. and import the resulting product into this country. This practice unfairly undercuts American inventors' rights and promotes unfair foreign competition in domestic U.S. markets.

This activity now constitutes an unfair method of competition within the scope of the Tariff Act [19 U.S.C. §1337(a)]. However this cause of action before the International Trade Commission is of limited use to aggrieved process patent owners. Not only must patent infringement be proved, but also the Commission must determine that the importation tends to "destroy or substantially injure an industry. . . . in the United States" [19 U.S.C. §1337]. Also, an Executive Order of exclusion must be obtained. In addition, the patent owner can only obtain this order of exclusion, and cannot obtain damages for past infringement.

The patent laws of the other industrialized countries do not permit this type of evasion of process patent owner's rights. Foreign manufacturers are protected and American manufacturers are not.

In our view, the only question of substance to be debated here is whether importation into the United States of products made by the process patented in the United States should or should not be an essential element of the remedy provided. In the 98th Congress, the House of Representatives passed a process patent bill which did provide that importation was an essential element. On the other hand, S. 1543 would allow an action for patent infringement whether the products were produced abroad by the protected process and imported or produced in the United States.

Except for those who profit by the exploitation of this weak point in the law, all agree that what must be stopped is damage to U.S. industry from this form of unfair competition by importation. However, we understand that the United States Trade Representative would prefer the broader bill, such as S. 1543, to avoid any possibility that it could be said to be inconsistent with United States obligations under the General Agreement on Tariffs and Trade.

We have two comments to make. First, there is no need which relates to the rights of process patent owners to have the broader bill. Process patent owners can currently take direct legal action against those who infringe their rights in the U.S. However, if S. 1543 were enacted, we believe the practical effort on cases involving domestic infringements of process patents would be negligible. In this type of situation, the patent owner and infringer are making and attempting to sell identical products in competition with each other. It is difficult to forsee a circumstance in which the patent owner would choose to mount a legal attack against his potential customers when the infringer/competitor and real source of the problem is with the jurisdiction of U.S. courts. Second, we fail to understand how this legislation could violate the GATT even if enacted in the narrowed form which relates only to imported products. The intended purpose and actual effect would be to provide protection to U.S. patent owners that which is currently provided to patent owners in virtually all of the industrialized countries of the world. In response to such GATT related complaints from foreign governments, we would suggest our Trade Representative explain that the U.S. Congress has only provided protection which they have already provided.

In closing, we quote to you an amended version of a familiar maxim: "necessity is the mother of invention and good legislation". The relief provided to inventors by S. 1543

was recommended by President Johnson's Commission on the Patent System in 1966, by President Carter's Domestic Policy Review on Industrial Innovation in 1979, and earlier this year by President Reagan's Commission on Industrial Competitiveness. In 1966, when America was the apparently unchallenged leader in the world of commercial technology, curing this defect in process patent owner rights may have only been a good idea. Today, we believe it has become a very necessary legislative step which should be taken now.

Thank you.

AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
SUITE 203 • 2001 JEFFERSON DAVIS HIGHWAY, ARLINGTON, VA 22202

Telephone (703) 521-1680

December 6, 1985

President
THOMAS F. SMEGAL, JR.
President-Elect
ROBERT C. KLINE
1st Vice-President
JOSEPH A. DEGRANDI
2nd Vice-President
JACK C. GOLDSTEIN
Secretary
JANICE E. WILLIAMS
Treasurer
LESTER L. HEWITT

Immediate Past President
ROBERT B. BENSON

Board of Directors
The Above Persons and
MAURICE H. KLITZMAN
WILLIAM L. LAFUZE
MARVIN PETRY
LAURENCE H. PRETTY
JEROME G. LEE
ROBERT M. NEWBURY
WILLIAM S. THOMPSON
SIDNEY B. WILLIAMS, JR.
ALBERT P. HALLUIN
I. FRED KOENIGSBERG
HERBERT H. MINTZ
HAROLD C. WEGNER

Councilman to NCPLA
LEONARD B. MACKEY

Executive Director
MICHAEL W. BLOMMER

Honorable Charles McC. Mathias
Chairman, Subcommittee on Patents,
Copyrights, and Trademarks
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Senator Mathias:

The following are the AIPLA answers to the questions you referred to us. We appreciate the opportunity to comment:

Question: Why is it necessary to hold the purchaser of the foreign product liable under the bill, if he uses or sells it in this country, rather than just targeting the foreign manufacturer who uses the patented process, then exports the product into this country? Why isn't it possible in all these cases to get jurisdiction over the foreign manufacturer, and so cut this activity off at its source?

Answer: If the "foreign manufacturer" does not carry on a business within the U.S., he is not within the jurisdiction of U.S. courts. The power of U.S. courts cannot be exercised outside of U.S. jurisdiction. It is true that in some types of criminal cases, the U.S. has bilateral treaty arrangements to cause foreign sovereigns to force persons to be brought within the jurisdiction of U.S. courts. However, no such arrangement exists regarding civil patent disputes.

Question: A process patentee bears the burden of proof in ITC proceedings, and in ordinary patent litigation, even if the defendant is an overseas corporation. Why should the burdens be allocated differently in cases arising under this legislation, if enacted?

Answer: We understand the question relates to the "presumption" provision proposed in the 98th Congress by the Department of Justice to legislation similar to S. 1543. The justification is that a defendant in these cases which has a business relationship either directly with the foreign manufacturer or with another U.S. business entity

which does is in far superior position to the plaintiff to ascertain how the product in question was made. In fact, establishing the "substantial likelihood" presumption as a condition of going forward to the defendant's case in chief only is possible after the plaintiff establishs that he was unable to ascertain the facts after making a reasonable effort to do so. We understand that the ultimate burden on the plaintiff to prove his case by a preponderance of the evidence to prevail is not changed by the provision in question.

Question: S. 1543, in contrast to the bill we considered in the 98th Congress, makes it an infringement to use or sell a product made by an infringement of a patented process in the United States as well as overseas. What practical difference does this addition make? How is the power to sue sellers of domestically-produced products likely to be used?

Answer: If the owner of the patented process is able to bring suit for infringement against the persons making the unauthorized use of the process in the U.S. he will do so. That is his competitor. We don't believe that a manufacturer will choose as an alternative course of action suing potential customers to coerce them into being customers. That is not the experience with other patented products where wholesalers or retailers may currently be potentially liable.

Question: What is likely to be the impact of this legislation on jobs here in the United States? As you know, the generic drug industry has argued that providing this protection would eliminate the incentive that exists under the ITC remedy to maintain manufacturing operations in this country. The ITC remedy requires a showing of injury to an efficiently run domestic industry. But if process patent protection were available under our patent laws, the generic companies argue, it would no longer be a requirement that the patentholder was manufacturing with his process in this country, and so he would probably shift his operations overseas to realize other economic advantages such as cheaper labor. How would you rebut this analysis?

Answer: As a preliminary matter, this "analysis" does not represent the view of the "generic drug industry." We understand from testimony to the Subcommittee that the Pharmaceutical Manufacturers Association represents 80% of that industry. By any measure then, the "generic drug industry" supports passage of S. 1543.

We presume this "analysis" comes from a group of small companies represented by the "Generic Pharmaceutical Industry Association." These companies are currently purchasing chemicals made in foreign countries and imported into the United States. The opposition of this group to S. 1543

leads us to conclude that they know that their foreign suppliers are producing these chemicals by use of processes patented in the U.S. Furthermore, they want to continue to purchase products made with foreign labor and not purchase products made with U.S. labor. The argument that the passage of S. 1543 and the resulting protection of U.S. industries from unfair foreign competition would in fact drive U.S. industries out of the U.S. into foreign countries represents, in our view, a near heroic effort in attempted advocacy.

The "analysis" is not an analysis, but a make weight argument which defies logic. A process patent gives the U.S. owner the right to exclude others from using the process to make a product in the U.S. The right is severely eroded if a competitor can make unauthorized use of the protected process outside the U.S. and then import the product into the U.S. No other industrialized country allows process patent rights to be evaded by this subterfuge. The U.S. Congress has recognized the unfairness of this activity and provided a limited remedy in the Trade Act.

To offer our "analysis", assume factory A in a foreign country and factory B in the U.S. are producing the same product using a process patented in the U.S. by the owner of factory B. Assume now that S. 1543 becomes law thus effectively prohibiting factory A from importing the product into the U.S. and competing with factory B. Does the passage of S. 1543 make it more or less likely factory B will prosper? Does the passage of S. 1543 make it likely that factory B will be closed and moved to a foreign country now that the foreign competition is eliminated? The answers are obvious.

Question: The Commissioner of Patents testified that S. 1543 should be amended to clarify that it applies only to products directly produced by the patented process. Do you have any comments on this suggestion?

Answer: The proposal as we understand it is to insert the word "directly" into proposed Section 271 to modify the word "produced." The problem with such a clarification is that the word "directly" is ambiguous in these circumstances. If it is not explained fully and with precision, there is danger that this word would create a loophole which would severely limit the use of the new statute.

We support the proposition that if a substance is made with the patented process and then changed into a wholly different substance by a second process and then that product is imported into the U.S., the owner of the patent on the first used process would have no cause of action against the seller

of the product ultimately imported. For example, if a patented process is used to make a heating fuel, and the fuel is burned in a second process to make aluminum which is imported, we agree that the owner of the heating fuel process should not be able to bring suit against the importers of the aluminum. However, if the patented process is a method of making aluminum, and that aluminum is turned into a baseball bat and imported, the owner of the process for making aluminum must be able to bring suit against the importer of the baseball bat. If he cannot, the statute will only apply to the importation of raw materials. The ability to change the form of the product produced by the process, or combine it with other products and thereby evade the statute would constitute a fatal defect in the law.

Question: The representative of the National Chain Drug Store Association, suggested that attorney fees should be awarded to the defendant if the plaintiff loses in a case brought under the bill (even if it was brought in good faith). What is your reaction to this suggestion? What, in your view, would a successful defendant have to show under the existing law of attorneys' fees to make out a claim of entitlement to attorneys' fees in a case brought under this legislation, if enacted as introduced?

Answer: We oppose imposing a mandatory penalty of any kind against a plaintiff who brings a patent suit in good faith and does not prevail. Furthermore, we know of no precedent in American jurisprudence for penalizing plaintiffs for failing to prevail.

Section 285 of Title 35 provides discretion to the court in "exceptional cases" to award attorneys fees to the prevailing party. In the case of a prevailing patent owner, such circumstances usually are willful or deliberate infringement. In the case of a prevailing accused infringer, such circumstances may be inequitable conduct by the plaintiff in obtaining the patent or pursuing the litigation. The section is bottomed on a finding of bad faith or unfairness.

If S. 1543 is enacted, we believe that Section 285 will prove to be as effective as it is in all other patent litigation.

Sincerely,

Thomas F. Smegal, Jr.

Thomas F. Smegal, Jr.
President

TFS:bm

Senator MATHIAS. Why wouldn't it be equally simple for the U.S. process patent holder to have a patent on his process in other countries?

Mr. SMEGAL. Well, Senator, the last time I counted there were almost 150 countries with patent systems, and there are a number of other countries that do not have patent systems. And in order for a U.S. process patent owner to provide for that circumstance, he would have to file 150 or so foreign patent applications, at what I might suggest to you is an incredible expense. Translations are required in most of these countries. It is just an incredible burden to place on someone who has taken the trouble to get a U.S. patent.

Senator MATHIAS. Enforcement would also have its problems.

Mr. SMEGAL. You have that problem. You also have the countries that have no patent systems where, certainly, a foreign manufacturer could set up a plant and import into the United States. It does not help. The problem is the importation of the product made by that process.

The other point they keep making is that somehow or other, this product—and they have admitted and agree it is a nonpatented product—well, implicit in that, is that product could be made by other procedures. The invention here that has been recognized under U.S. law is a unique process, a unique way of making a product that is already known—as Mr. Mossinghoff mentioned, the situation with the drug industry—these compounds could be compounds that occur in nature, the process has been developed at great expense and subjected to the U.S. patent process and patented, or procedures which may improve the quality of that particular known product, or it may produce it in a way that is cheaper. And that is what we are looking at here.

We have got a patent; it has some advantages in the marketplace. That is why it is being used, that is why it is being copied, that is why the foreign manfacturers are using it. There are some advantages. There are other ways to go. If they do not want to buy a particular drug that has a particular ingredient that was manufactured by the patented process, there are other ways to get those ingredients. They are known ingredients, they are not patented ingredients.

The advantage here is because the particular process is unique, beneficial, in terms of the cost to manufacture through it, or the quality or the purity of the product.

Senator MATHIAS. Dr. Fryer, let me ask you a question on a presumption issue. If a case were to be brought under this bill, should it be enacted into law, it would differ in some degree from ordinary litigation in that in most cases, the infringing manufacturer, or the alleged infringing manufacturer, would be somewhere else, beyond the reach of the writ of the United States, and so would presumably not be subject to discovery proceedings.

Now, this makes producing evidence of infringement considerably harder than in the domestic case. Under those circumstances, isn't some presumption justifiable?

Professor FRYER. It is a tough problem—the degree of presumption that is required and how a particular court will use it, and

how that approach will differ from the existing burden that the plaintiff, the patent owner has to win its case.

I have no research data which would support an opinion that I heard, but it appears true, that in these other countries where the process product is protected, they have been able to find infringement of the product by the manufacturer using the patented process. The fact that all these countries have this type of law indicates to me that they have been successful in effectively preventing the manufacture of particular products made by a patented process, so there must be, just to use a pun, a presumption that no special rule creating a presumption on who has the burden of proof is needed. I have had some conversations with persons from drug companies, informally, that suggested they have been successful in enforcement of similar laws without a special presumption rule. It is very difficult for the patent owner in some cases to come up with enough evidence to prove infringement where the manufacturer is overseas. This situation puts the patent owner of the improved process under difficult burden of evidence-gathering, and he might lose more of his cases where the manufacturers are overseas. The question remains whether the U.S. sellers and users should take the burden to gather the evidence, by shifting the burden to them, at the risk of being liable if they fail to come up with the evidence from the overseas manufacturer.

So how far should we go with a law to get at an overseas manufacturer. The question is the manufacturer's likelihood of disclosing trade secrets and the balance that might have to be provided here to protect the U.S. sellers and users, in terms of what realistically they can force the overseas manufacturers to do.

So when you balance those two parts of the equation, you come up to an answer that may be the proper line to draw is the present line in terms of the burden of proof being on the patent owner, which seems to work, while it may be difficult in some cases for the patent owner.

Senator MATHIAS. Mr. Smegal.

Mr. SMEGAL. Senator, I was just going to say that I try cases on occasion when I am not being president of this organization, and certainly, there are many circumstances under existing law where matters would be subject to a protective order; I do not see that as a particular sticking point in this legislation. There are ways to protect and to keep matters in camera before this courts.

Senator MATHIAS. One problem that the opponents of this legislation have raised I think deserves just a word. You are not only president of the Intellectual Property Law Association, but you are a member of the board of the Legal Services Corp., I believe.

Mr. SMEGAL. Yes, sir.

Senator MATHIAS. You know that although the patent lawyers by and large have escaped most of the criticism that the rest of the bar gets, there may even be "bad apples" among patent lawyers, and that frivolous cases are not unheard of.

What about the criticism that this legislation will expand the opportunity for the misuse of the judicial system—coercion or intimidation of the defendant?

Mr. SMEGAL. Yes, Senator, I think we already have that circumstance well covered in the statute. United States Code, title 35, sec-

tion 285, I believe, provides for attorneys' fees in exceptional cases, and I would think—I have not researched this point—but I would assume and feel very strongly that frivolous lawsuits would certainly fall into the category of an exceptional case which would provide for attorneys' fees under section 285. I do not see this as a problem at all.

That is certainly the situation we have right now. What if someone is sued on a product on their shelves, and it turns out that the patent covers the wall hangings rather than the particular gadget? That situation exists now. You would go to the court and you would say, "I have got an exceptional case, Your Honor. It is under section 285 of title 35. I am entitled to attorneys' fees." And assuming you have a judge who understands that issue, you are going to get attorneys' fees. And if it is a frivolous suit under these circumstances, they are going to have their opportunity to present the evidence of that, and they are going to prevail.

Senator MATHIAS. Well, I regret that this hearing has been interrupted so often this morning and has delayed you, particularly after you made the trip from San Francisco. Professor Fryer has only had to make the trip from Baltimore.

Mr. SMEGAL. I am honored by the opportunity to make a presentation, Senator, and I thank you for your time.

Senator MATHIAS. But because of the interruptions and because of the fact that other members have been necessarily required to be other places, I am going to ask you to respond, or at least to be prepared to respond, to possible written questions which will be posed, and your answers will be included as part of the record.

In order that that may be possible, I am going to direct that the record be left open for 30 days, and if during that time you wish to add anything to your own statements, we will be glad to receive that as part of the record. So the record will be kept open for 30 days.

The committee will now stand in recess subject to the call of the Chair.

[Whereupon, at 1:17 p.m., the subcommittee was adjourned.]

APPENDIX

ADDITIONAL SUBMISSIONS FOR THE RECORD

TESTIMONY OF NEW YORK PATENT, TRADEMARK AND COPYRIGHT LAW ASSOCIATION ON SENATE BILL S.1543

Introduction

The New York Patent, Trademark and Copyright Law Association strongly supports the enactment of legislation granting additional, and needed, protection to holders of U. S. process patents. We make the following suggestion to improve S.1543, so that it will provide an effective remedy to the patentee without placing new and unnecessary burdens on domestic manufacturers and retailers.

Summary of Suggested Improvement

We suggest that the extension of liability provided by the bill be limited to persons who import or make the first sale in the United States of the product produced by the patented process.

Background

Under our present patent law, the inventor of a new and technically advantageous process is denied exclusive enjoyment of the benefits of his invention when a person who actually practices that process is not amenable to suit, even though the product produced is ultimately introduced into commerce in the United States. This results in substantial diminution of the value of process patents and, therefore, the incentive to make process inventions and

55-522 O - 86 - 8

disclose them to the public. Inventors are encouraged, instead, to keep their process technology secret to avoid its appropriation by others against whom the inventor has no redress under the patent laws.

To encourage both innovation and dissemination of technical information, process patentees should be provided more extensive remedies than they now have, as S.1543 intends to do. Our association supports, and urges adoption of, legislation that will effectuate that intent.

In making our suggestion for improvements in the bill, we are mindful of the fact that the principal cause of unfairness is the use of the patented process by foreign companies, outside the reach of the present patent law, who then directly or indirectly introduce the product into United States commerce. Legislation closing that loophole may well be all that is required. The patent holder, whether U. S. or foreign, already has a direct remedy against persons who carry out the patented process in the United States. We also are mindful, however, of the consideration that the legislation should not be, or even appear to be, discriminatory against our trading partners.

Suggested Improvement

S.1543 would attach liability for infringement of a process patent not only to importation of the product, but also to every sale or use of that product in the United States. While we believe that process patentees need an effective remedy against unauthorized use of their technology, our concern is that the remedy proposed goes beyond what the patentee needs. Imposition of liability on users and sellers who are several steps remote from the person who actually uses the process technology may create an unwieldy and unnecessarily burdensome system.

Our suggestion is that the acts of infringement be defined as the importation into, or the first sale in, the United States of the product produced by the patented process. Subsequent sellers and users of the product would, under our proposal, not be infringers of the process patent.

The best explanation of the reasoning underlying our proposal is by way of an illustrative example. Assume Company A holds a patent on a process for making rubber. Company B (a domestic manufacturer) makes rubber which it sells to a tire manufacturer, who sells its tires to an automobile manufacturer, who sells its cars to consumers. Under the present bill, charges of infringement of the process patent could be made against every person in that chain.

The patentee's rights normally will be adequately protected if he has a remedy against the first person who introduces the rubber into United States commerce. That person also will be the United States entity in closest proximity to the person actually carrying out the process and, therefore, the entity that can most effectively know, and control, the process technology used. Where the process is carried out by a domestic manufacturer, it normally will make the first sale. Thus, under our suggestion, there would be no expansion of the current liability of domestic manufacturers and retailers for patent infringement.

If liability for infringement is not cut off at the first sale or importation, Company B will, as a practical matter, be required to indemnify people remote from it in the chain of distribution. It will run the risk of being forced to defend a plurality of suits in inconvenient forums. Even absent a charge of infringement, it may be forced to disclose its secret process technology to a series of users and sellers to reassure them, or allow them to make their own determination, that they are not indirect infringers of

any existing process patents. Furthermore, each person in the chain of distribution usually would be warranting, under Section 2-312(3) of the Uniform Commercial Code, that the product it delivers does not infringe a process patent. Even if such a warranty were expressly excluded, those persons may be deemed joint tortfeasors (infringers) with joint and several liability. Going back to our example, if the patentee chooses to sue the tire manufacturer, and the value of the tire greatly exceeds the value of the rubber raw material, Company B may face damage liability far in excess of the revenue it derives from selling the rubber.

Because importation or first sale would become acts of direct infringement, a foreign manufacturer could be liable as an active inducer of that direct infringement, notwithstanding that the foreign manufacturer did not conduct any infringing activity in the United States, by application of existing law. See, for example, Honeywell, Inc. v. Metz Apparatewerke, 509 F.2d 1137 (7 Cir. 1965), Engineered Sports Products v. Brunswick Corp., 362 F.Supp. 722 (D.Utah 1973) and Hauni Werke Koerber & Co., K.G. v. Molins Ltd., 183 USPQ 168 (E.D.Va. 1974). Thus the holder of a U. S. process patent could have a remedy directly against the foreign manufacturer.

In summary, our Association believes that S.1543 can be improved by a more careful balancing of the needs of process patentees and the burdens imposed on domestic manufacturers and retailers. That balance can be achieved by defining, as acts of infringement, the importation into the United States, or the first sale in the United States, of a product made by a patented process.

Proposed Amendments to S.1543

In the amendment to Section 154 of Title 35,

delete "using or selling products produced thereby throughout", and substitute --making the first sale in the United States of a product produced thereby--; and delete the comma after "into".

In the amendment to Section 271 of Title 35, delete "uses or sells" and substitute --makes the first sale--.

Further Comments

Our Association understands that other Associations and interested groups will present testimony favoring the deletion of the pre-existing rights provisions of S.1543 and the addition of the presumption provisions found in H.R. 1069 (as proposed new Section 295 to Title 35). We support those proposals but believe it is unnecessary for us to add to the record concerning them. We do note that the presumption provisions, if included, would require revision (by changing "use or sale" to --importation or first sale--) to conform to our suggested amendments to the other sections.

John O. Tramontine, President
The New York Patent, Trademark
and Copyright Law Association

THE NON-OBVIOUS REASONS WHY S-1543 SHOULD BE ENACTED*

Representatives of industry and the patent bar have articulated cogent reasons why S-1543 should be enacted. Briefly stated, these reasons are:

1. Many commercially significant inventions are new processes for producing old (i.e., unpatentable) products. When such a process is practiced in another country and the product is sold here, the commercial impact occurs in the U.S., but the law does not provide adequate relief.

2. The only remedy now available is an ITC proceeding which, in many instances, is no remedy at all because relief may be denied based on factors having nothing to do with the merit of the invention and, in any event, damages cannot be recovered.

3. Because of factors 1 and 2, infringers construct plants outside the U.S. and jobs in this country are lost.

4. The laws of other major countries provide effective relief in the same situation. Amendment of the U.S. law would harmonize our laws with those of other such countries.

Although these reasons are persuasive, they tell only half the story because they address only a deficiency in U.S. law. Equally compelling, although more subtle, are presently existing provisions of U.S. and foreign laws which, in combination, may function to deny U.S. companies any real protection for process inventions. This combination of factors has not, I believe, been clearly identified for consideration by this Committee.

In the following comments, I shall briefly describe the significance and function of these laws. Thereafter, through a hypothetical example, I will describe the impact of these laws on a U.S. company. In conclusion, I shall establish that most foreign countries are way ahead of the U.S. in utilizing their patent laws to promote their own trade policy. To provide some small balance, the proposed process patent bill should be enacted.

*Written testimony in support of S-1543 submitted by Alfred L. Michaelsen, General Patent Counsel, Corning Glass Works, Corning New York, 14831.

I. U.S. VERSUS FOREIGN LAWS

A. Secretly Used Processes

A basic goal of U.S. patent law is to promote the early disclosure of new inventions. In return for a prompt and full disclosure of a patentable invention, the inventor is awarded a patent. This policy is manifested in 35 U.S.S. 102 which provides, inter alia, that an inventor may not obtain a valid patent if he commercially practices his invention for more than one year before filing his patent application.

Decades ago, U.S. courts considered the situation where a patentable process is invented and is "secretly" used commercially to make a product which is sold. "Secretly" means that the use of the process is not detectable by inspecting the product. The courts held that such a use defeated the right to a patent because it was contrary to the policy of encouraging prompt disclosure of new inventions.

Most foreign countries have not adopted this view. Instead, the philosophy is that anything is patentable if it is new, nonobvious and not publicly known. Thus, in these countries, a company may commercially but secretly practice a process for years and then apply for a patent. And, within one year after applying for the foreign patent, the foreign company may apply for a U.S. patent and not be troubled by U.S. law because it had not used the invention in this country prior to its filing in the U.S.

Thus, U.S. companies must promptly file a patent application on a new process which is to be used commercially but "secretly". Foreign inventors carry no such burden.

B. U.S. Law Requires "Full Disclosure"

Our patent law (35 U.S.C. 112) requires, inter alia, that an inventor disclose in his patent application what he regards as the "best mode" for practicing his invention. In the case of a patent application on a process, this requires a full disclosure of all relevant process conditions (e.g., pressure, temperatures, times), as well as a disclosure of any required uncommon starting materials and any apparatus or equipment used to practice the process and which is not commercially available and known.

The patent laws of the European Patent Convention (under which most of the countries in Western Europe operate), as well as the patent laws of Mexico and Japan, do not require such a disclosure.

C. Mandatory Licensing

The patent laws of Canada, Japan, Mexico, Great Britain, West Germany, Italy, France, Holland, Brazil, Taiwan and Argentina all include mandatory patent licensing provisions. Although there are minor variations from country to country, basically these laws all operate as follows. Within a designated period after the issuance of a patent (usually three years), the invention claimed in the patent must be "worked", i.e., actually practiced within that country. Failure to "work" the invention within the country is denominated an "abuse" of the patent.

If the invention is not actually used in that country within the prescribed time, any party may apply to a designated government agency and obtain a so-called compulsory or mandatory license under the patent if it is "in the public interest". The license is granted by the government of that country and the patentee cannot prevent it. Indeed, the foreign government not only has the power to grant licenses without the consent of the patentee, it is obligated to grant a license if the applicant for the license proves that the invention has not been used within the prescribed time. And, the designated government agency not only has the power to fix the royalty rate to be paid but, in addition, may in certain countries grant to the applicant an exclusive license whereby the patentee is prevented from practicing his own invention in that country!

With respect to activities which constitute practicing the invention, in the case of a patent on a product (e.g., a computer chip) or an apparatus (e.g., a machine tool such as a milling machine), it is not enough that the patentee sells the product in that country. Instead, to constitute "working" or "actual use", the product or apparatus must be made in that country. With respect to a process invention, the situation is particularly ironic. Thus, as indicated earlier, in virtually all foreign countries it is an infringement of a process patent to sell an unpatented product in that country which was made elsewhere by a process patented in that country. However, when it comes to mandatory licensing, it does not constitute "working" of the process to practice the process outside the country and sell the

product of the process in that country. Instead, the process must be practiced within the country.

D. Unenforceability of Foreign Process Patents

If one owns a patent on a process for producing an old product, e.g., gasoline, it seldom happens that one will have direct evidence of infringement by another. In such a situation, the patent owner usually will only have a belief that infringement is occurring. In the U.S., evidence of infringement is obtained through "discovery", i.e., the rules of civil procedure provide that the plaintiff may compel the defendant to disclose the details of the accused process.

In certain countries, e.g., Japan, the rules of civil procedure simply do not allow for such "discovery". In Japan, it is presumed that a process used by a company is a trade secret and disclosure to another party will not be compelled. The result is that, essentially, patents on processes for making known products are not enforceable in such countries.

E. The "Second Inventor"

If a company invents a new process and the details of the process cannot be discerned by examining the product, e.g., a new gasoline refining process, considerable thought will be given to keeping the process a trade secret because policing a patent on such a process can be difficult, even in the U.S. However, recent U.S. case law suggests that such an approach may be hazardous.* Specifically, the hazard relates to the possibility that another company will later invent the same process, obtain a patent and then assert the patent against the "first inventor". In the U.S., it now appears to be the law that, in such a circumstance, the "second inventor" may obtain an injunction against the "first inventor".** The consequence is that U.S. inventors are best advised to seek patent protection when such an invention is made.

---

*D. L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1287 (CAFC 1983)

**When a method is kept secret, and remains secret after a sale of the product of the method, that sale will not, of course, bar another inventor from the grant of a patent on that method." Id. at p. 1291

In contrast, the laws of many foreign countries provide that, in such a situation, the patent owned by the "second inventor" cannot be asserted against the "first inventor" who has commercially been using the invention. Consequently, in these countries, there is not the impetus to file and disclose new processes which exists in the U.S.

II. A HYPOTHETICAL EXAMPLE

As indicated earlier, these differences between U.S. and foreign laws are not obviously relevant to the proposed legislation. A hypothetical example demonstrates that relevance.

Let us assume that the Acme Shoe Company of America, a company that has been making shoes in the U.S. for many years, invents a radically new shoe making process. Let us further assume that a plant to practice the new process is capital intensive and, therefore, is economic only if there is foreseeable access to a significant portion of the market. Finally, let us assume that, as frequently is true, it is not possible, by examination of the product, to detect if the product was made by the new process.

Acme decides to commercialize the process because it represents its last hope for competing with foreign manufacturers. Because of the capital intensity of the new process, Acme must commit a major portion of its financial resources. And, because its R&D investment has been substantial and its manufacturing commitment will be even greater, Acme realizes that it must have a proprietary advantage for a least seven years after commencement of full scale commercial production. Thus, Acme seeks the guidance of its patent counsel.

Acme asks its patent counsel - 'should we seek patent protection or should we maintain the process as a trade secret?' Acme's attorney advises that Acme should seek patent protection because of the risk that another company may later make the same invention and obtain a patent and then shut down Acme's plant. Also, Acme should seek a patent promptly because, unlike most foreign countries, one cannot obtain a valid U.S. patent on a process if it has been commercially (albeit secretly) used within this country for more than one year. Acme is convinced and instructs its attorney to file a U.S. patent application and later to file corresponding patent applications in Japan, Canada,

Mexico and other foreign countries. The U.S. application is filed and Acme begins building its plant.

Eighteen months later, Acme's plant is nearing completion and, in accordance with Japanese patent law, the Acme patent application is published. Acme's Japanese patent application contains a full and complete description of the process because the Japanese patent application must (under Japanese law) correspond to Acme's U.S. application and U.S. law required that Acme's U.S. application contain a full and complete disclosure of the invention. Thus, before Acme finishes building its plant, its Japanese competitors are fully informed of the details of the Acme process.

Acme de-bugs its new plant during the second year and begins production at the end of the third year. Meanwhile, Acme's attorneys, by diligence and remarkable luck, have obtained Japanese, Mexican and Canadian patents which correspond to its then issued U.S. patent. Acme begins to increase its market share through reduced prices permitted by reduced manufacturing costs. However, in order to recover its investment, Acme will need seven more years of improved sales, i.e., through year ten.

During years four and five, Acme considers building plants in Mexico, Canada and Japan. However, it concludes that the markets in those countries are not sufficiently large for it to capture a market share that would justify the substantial capital expense. Thus, it decides to rely on its patents in those countries to protect against foreign competitors using the Acme process.

During the latter part of year six, Acme begins to encounter strong price competition from foreign competitors exporting from Canada, Mexico and Japan. Acme hires a consultant who investigates the matter. In the middle of year seven, the consultant reports that Acme's competitors must be using the Acme process because, otherwise, they would be selling under their variable cost.

Acme decides first to confront the Canadian infringer. The parties meet and Acme accuses the Canadian company ("Canco") of infringing and demands that Canco "cease and desist". Canco acknowledges that it is using the Acme process in a pilot plant and says that it will take a nonexclusive license and pay a royalty of 2%. Outraged, Acme rejects the offer. Canco then

explains that if Acme does not grant the requested license, Canco will seek a compulsory exclusive license and will, thereafter, prevent Acme from importing shoes into Canada. Acme responds that that is preposterous. Canco's Canadian patent counsel then condescendingly explains Canadian law. He explains that, under § 67(1) of the Canadian Patent Act -

> ". . . at any time after the expiration of three years from the date of the grant of a patent, [a party may] apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief". (Emphasis added)

Canco's counsel then explains that § 67(2) of the Act defines six forms of "abuse". In summary, they are -

> (a) the patented invention is not being worked in Canada on a commercial scale and no satisfactory reason can be given for such non-working;
>
> (b) the working of the invention in Canada is being hindered by imports into Canada from the patentee [Acme];
>
> (c) "the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms";
>
> (d) the patentee refuses to grant a license and, as a result, "the trade or industry of . . . any person . . . in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a license . . . be granted";
>
> (e) any person engaged in a trade or industry in Canada "is unfairly prejudiced by the conditions attached by the patentee . . . to the license . . . of the patented process";
>
> (f) that the patent relates to a process and the patentee has utilized the process "to prejudice the manufacture, use or sale of the product of the process".

Finally, Canco's counsel tells Acme that § 67(3) of the Act provides that -

> "For the purpose of determining whether there has been any abuse of the exclusive rights under a patent, it shall be taken, in relation to every paragraph [set forth above], that patents for new inventions are granted not only to encourage invention but to secure that new inventions shall so far as possible be worked on a commercial scale in Canada without undue delay." (Emphasis added)

Canco's counsel then says that it is plain that Acme has "abused" its Canadian patent because at least one of the six

paragraphs set forth above describe the present situation. Finally, Canco's counsel points out Canco may seek an exclusive license under Acme's patent by proceeding under § 68(b) of the Act which provides that -

> "if the Commissioner is satisfied that the invention is not being worked on a commercial scale within Canada, and is such that it cannot be so worked without the expenditure of capital for the raising of which it will be necessary to rely on the exclusive rights under the patent, he may, unless that patentee . . . will undertake to find such capital, order the grant to the applicant . . . of an exclusive license on such terms as the Commissioner may think just . . . ". (Emphasis added)

Canco's counsel says that Canco plans to build a full scale plant and asks if Acme "will undertake to find such capital" as Canco will need to build its plant to practice the Acme process. If Acme will not provide such an undertaking, Canco magnanimously would, in place thereof, accept a 2% nonexclusive license. Acme says that it will consider the matter and contact Canco later.

Concluding that it fared poorly by traveling north, Acme decides to head south and confront the Mexican infringer. The Mexican company ("Mexco") does not deny that it uses the Acme process. However, Mexco does contend that Acme has not met its obligations under Mexican law. Mexco's counsel points out that Article 41 of the Mexican patent law provides that -

> "The granting of the patent implies the obligation of exploiting it in the national territory. The exploitation must be initiated within a period of three years counting from the date of issue of the patent." (Emphasis added)

Mexco's counsel also points out that Article 43 provides that -

> ". . . exploitation is the permanent utilization of the process patented . . . , performed directly by the holder of the patent, his assignees or licensees, in such volume as corresponds to an effective industrial exploitation and in appropriate conditions of quality and price.
>
> "The importation of the product covered by the patent of a product manufactured with the process patented will not be considered to be exploitation."

Thus, says Mexco's counsel, Acme has not "exploited" the patented process in Mexico by importing into Mexico the product

made by the process in the U.S. Still further, Mexco's counsel points out that Article 50 specifically provides that one may apply for a compulsory license in the following circumstances -

> "III. When exploitation of the patent does not satisfy the national market.
>
> "IV. When there exists export markets which are not being covered by the exploitation of the patent and some person manifests his interest in utilizing the patent for purposes of exportation."

The Mexco businessmen opine that Acme's exploitation of its patent has "not satisfied the national market" and, in Mexco's view, the United States constitutes an "export market which is not being covered by the exploitation of the patent", and Mexco surely has an interest in that market.

Finally, Mexco's counsel says that Mexco probably will not even bother applying for a compulsory license because, in a few months, Acme's Mexican patent will lapse anyway. He explains that this is a result of Article 48 of the Mexican patent law which provides that -

> "The patent will lapse if, when the term referred to by Article 41 [i.e., three years from issue] has expired, more than one year should pass without the patent holder initiating its exploitation, and if during this final period no obligatory licenses have been applied for."

Mexco's counsel notes that Acme's Mexican patent issued three and one-half years ago and, in six more months, it will lapse. Acme says that it will consider the matter.

Acme then decides that it will confront the Japanese infringer. The Japanese company ("Japco") receives Acme with great courtesy and ceremony. Acme expresses its belief that Japco is infringing the Acme Japanese process patent. Japco assures Acme that Japco is not using Acme's process but, instead, uses a process that was invented in Japan long before the Acme process was invented. Acme asks that Japco explain the process. Japco says that, in Japan, the process which a manufacturer uses is a trade secret and Acme cannot really expect Japco, a competitor of Acme, to disclose its trade secrets. To reassure Acme, Japco points out that if it were using the Acme process, it would have asked for a license from Acme and would have been confident of receiving such a license because, if Acme had not granted the license, Japco could obtain a compulsory license from

the Japanese Commissioner of Patents under Article 83 of the Japanese patent laws.

Acme is convinced that Japco is using the Acme process and consults a Japanese patent attorney. Acme explains the facts and asks the attorney to start a patent infringement suit against Japco. The Japanese attorney patiently explains that such a suit would be doomed to failure because Acme has no proof that Japco is using the Acme process. Acme is no stranger to U.S. litigation and confidently responds that such proof can be obtained through discovery. With even greater patience, the Japanese attorney explains that, under the civil procedure laws of Japan, it is not possible, in a patent infringement suit relating to a process, to compel the defendant to disclose the process which it uses because, in Japan, such information is considered to be a trade secret. The attorney says that the only exception occurs when the product of the process is a new product but, obviously, that exception does not apply with respect to the product of the Acme process.

So that the Acme people will have something to read on the way home, the attorney gives them a copy of an article which appeared in the June 1985 edition of the publication A.I.P.P.I.* The article is entitled On The Actual Situation Of Lawsuits For Patent Infringement In Japan. On the way home, the Acme people take special note of the following two sentences which appear in the Conclusion of the article -

> "The basic idea is that before filing a lawsuit [in Japan] the plaintiff must ascertain the fact of the defendant's infringement and have evidence thereof in hand. A plaintiff having no definite data as to the fact and expecting to discover evidence in the defendant's internal materials in the course of the legal proceedings process can almost never get a favorable judgment."

During the flight home, the Acme people conclude that they will have to be content with the protection afforded Acme by its U.S. patent. They conclude that they will instruct their U.S. patent counsel to commence an infringement suit against the foreign manufacturers. Shortly after their arrival, Acme's U.S. patent counsel tells them that it is not an infringement of Acme's U.S. patent when the Mexican, Canadian and Japanese

*A.I.P.P.I. is the Quarterly Journal of the Japanese Group of the International Association for the Protection of the Industrial Property.

companies sell shoes in the U.S. which are made by the Acme process.

III. CONCLUSION

I do not suggest that my hypothetical example is something which regularly occurs. Nevertheless, it is certainly true that knowledgeable U.S. companies are well aware of the constraints and pitfalls which are embodied in foreign patent laws and the significant differences between U.S. and foreign laws. And, that awareness directs their activities so as to avoid the problems which Acme encountered, i.e., there is a strong motivation to either forego any efforts to obtain a foreign patent or, if one is obtained, the motivation to license is substantial. Thus, once the foreign process patent is licensed, the commercial impact is felt in this country and the U.S. patent laws provide no relief. With respect to the foreign license, a nominal royalty is a poor substitute for the exclusive rights which a patent is suppose to provide.

Putting aside the likelihood that an Acme situation would occur, the significant factor to appreciate is that foreign countries have, for years, implemented trade policy through their patent laws. The statutes cited above clearly evidence the following policy - if you want a patent in our country, you better be ready to practice the invention in our country.

It is clearly the law in this country that a patentee need not practice his invention. He may, if he desires, supress it for the full 17-year term of his patent - that is his privilege in return for a full and timely disclosure of his invention. As we have seen, this is not the law of foreign countries and this difference has profound impact on process inventions.

In order to practice a process invention, one must build a plant or modify an existing plant. Generally, there is a relation between the commercial significance of a new process and the cost of constructing the facilities to practice it. I suggest that foreign countries are not oblivious to this fact. Instead, it has been recognized and these countries have affirmatively acted, years ago, to ensure that, to the extent possible, new processes are practiced in their countries for the benefit of that country's national ecomony and for export. The

result is a loss of jobs and financial reward in this country and a corresponding gain to foreign countries.

The present deficiency in U.S. law regarding process inventions fits hand-in-glove with the manifest goals of foreign countries. Foreign governments seek to ensure that U.S. invented processes are used in their country and U.S. law provides no protection when they are successful. This bizarre, asymetrical situation should be rectified promptly by enacting S-1543.

U.S. PROCESS PATENT PROTECTION: THE NEED FOR EXTRATERRITORIAL EFFECT -- THE BIOTECHNOLOGY INDUSTRY AS A CASE STUDY

Kenneth J. Woolcott
Trade Regulation Seminar
The National Law Center
The George Washington University
Spring 1985
Professor Glen Weston

I. INTRODUCTION

> [B]y special legislation in regard to patents, and these temporary and temporizing modifications of our patent laws, we have now got a system which I venture to say no Senator will rise on this floor, and assert that he understands. Ever since I have had the honor of a seat in this body the patent laws have been the subject of dispute, and I have rarely found any one instance where any two senators agreed in the construction of the laws. The patent laws have been so modified to suit particular cases year after year, from the very first patent law to the present time, that no one can understand them. This, too, will add to the compilation of our system of patent laws. Now so far as I have been able to look into them, and inquire into their operation, they are mere traps. They have actually created systems of attorneyships and agencies, which stand like so many hawks, ready to pounce upon and confuse any man's mind when he has made an invention.... To my mind, if we pass this bill, we start a horde of patent missionaries through this country, to hunt up and follow every article of manufacture through the country, and institute suits to fill our courts of justice with litigation; and whether they protect the rights of the original patentee or not, they take care to fill their own pockets in the course of the operation.
>
> Senator Borland (AK), June 14, 1852.[1]

The idea of extraterritorial protection of U.S. patented processes has been the topic of legislative debate for well over a century and clearly is not a novel proposition, but the solution to the problem of unauthorized importation of goods made by such processes remains ellusive. After 133 years, many of Senator Borland's concerns remain valid, i.e., the increasing

---

Note.--Footnotes at end of case study.

complexity of the patent laws, the plight of the individual inventor, the overburdened court system, and the practical difficulties of enforcing process patent rights by vicariously policing the products of the process. Also remaining substantially unchanged over the 133 years are the U.S. patent laws relating to the protection of process inventions.[2] Under current U.S. law, the unauthorized importation into the U.S. of articles produced abroad by a process patented in the United States does not constitute infringement. In other words, only the unauthorized use of the patented process in the United States is prohibited. In contrast, where the invention is a product the patentee[3] can exclude others from making, using, or selling the patented item in the United States.

The nature of the U.S. economy and international trade has not, however, remained correspondingly static. Instead, dramatic changes have ensued whereby today's threat to the United States' leadership in technology and trade is not limited to "wooden articles" or imports from "adjoining territories."[4] The threat comes from intense global competition in all areas of technology. Yet despite this evolution, in some cases revolution, in technology and trade, the United States has the dubious distinction of standing alone among the world's major trading nations in offering territorially limited protection of process inventions.[5]

The President's Commission on Industrial Competitiveness highlighted the practical consequences of this anomoly in our patent laws in its 1985 report: "Perhaps the most glaring deficiency in America's technological capabilities has been our failure to devote enough attention to manufacturing or 'process' technology."[Emphasis added.][6] Attention to process and manufacturing technology, whether patentable or not, pays dividends. For example, Japan invented neither the automobile nor the semiconductor chip, but through innovations in process and manufacturing technology the Japanese are capturing major

world market shares based not on esoteric products, but on high quality, low cost goods. The importance of process innovation is not limited to old industries with established products. The infant biotechnology industry may, by virtue of its technology and the market for its product, be very "process intensive" during its first ten to fifteen years. The U.S. biotechnology industry's international competitiveness may be affected by enhanced process patent protection.[7] Although the disparity between the U.S. competitive position in process technology, as compared with product technology, cannot be explained completely on the basis of the current loophole in U.S. patent protection for process inventions, enhancement of intellectual property protection would most certainly mean a fundamental step toward increased innovation and the subsequent application of process technology.

The need to enhance our international competitiveness in technology and trade has not gone unnoticed. During 1983 and 1984, the Reagan Administration and a number of members of Congress proposed packages of legislation to stimulate research and development that included bills to extend patent protection to products produced by patented processes.[8] Although the debate over the current "process patent legislation" has not invoked an oratory of concern equal to that of Senator Borland[9], the concept of extraterritorial process patent protection remains a controversial but increasingly important industrial trade policy issue.

This paper examines the various impacts of current and proposed means for protection of process inventions in the U.S. It considers the rationale for our unique territorial patent protection of processes, and whether the International Trade Commission remedy currently available to process patent holders is adequate in today's global marketplace. Also, as a case study, this paper examines the potential impact of extended process patent protection on an important new industry -

biotechnology. Finally, it makes recommendations as to the type and scope of intellectual property protection necessary to improve our competitive position in process technology.

II. THE PURPOSE OF THE PATENT GRANT

To many people, the term "patent" and the idea of restricting importation of goods into the United States are synonymous with the antitrust definition of "monopoly" and the trade concept of protectionism. Nothing could be more detrimental to a discussion of extending process patent protection than to begin under these misnomers. It is important to understand at the outset that patents rarely convey monopoly power and that enhanced process patent protection would benefit all U.S. patentees, both U.S. and foreign citizens.

The Constitution grants Congress the power "[t]o promote the Progress of Science and the useful Arts, by securing for limited times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries."[Emphasis Added][10] A patent, under the statute enacted pursuant to this power, is given all the attributes of personal property.[11] Accordingly, the patent grant gives the patentee an exclusionary (not affirmative) right, which the essense of personal property.[12] Our law does not give the inventor the right to practice the patented invention; it only allows the patentee to prevent other from using the patented invention.

For example, if inventor A receives a patent covering the digital watch and inventor B makes a patentable improvement to the basic concept of the digital watch, e.g., the liquid crystal display ("LCD"), inventor B cannot make, use, or sell his LCD watch without infringing A's basic digital watch patent. However, B can use his patent rights to prevent A from making the LCD watch. The net result is that, A must make old-fashioned digital watches (e.g., an "LED"), B cannot make the LCD watch, and the public cannot purchase the LCD watches that it wants.

Well, lets assume A and B solve this problem by coming to an agreement whereby they can use each others inventions and both make the LCD watches (a cross-license). Inventors A and B now have a "monopoly" in the watch market and can charge the public a monopoly price for the LCD watches, right? Wrong.

As is almost always the case, the public can find an acceptable substitute for the patented item, in this simplistic example the alternative might be an analog watch. Moreover, the patentee is not attempting to monopolize something that had previously been freely available to the public, but rather the patentee through his invention is offering the public something that did not exist before.[13] As Chief Judge Markey has recently stated "[i]t is but an obfuscation to refer to a patent as 'the patent monopoly' or to describe a patent as an 'exception to the general rule against monopolies."[14]

At first blush, any attempt to restrict importation sounds like protectionism and would seem to run against the grain of the Reagan Administration's committment to "free-trade." The Constitutional objective of the patent laws is, however, the promotion of science and technology, not international trade regulation. Congress has seen fit, and wisely so, to offer the the protection of our patent laws to foreign as well as U.S. citizens. In this regard, Chief Judge Markey's comments again are noteworthy:

> Nortron's brief characterizes Schenck as a "German monopolist." That denigration, whether inserted in a vain hope of prejudicing the court or otherwise, has no support in the present record. Disclosure of an invention found to have revolutionized an industry is but a classic example of the ideal working of the patent system. If a patentee or licensee enjoys widespread sales, that too is but an example of the incentive-useful arts promoting element in the patent system. Patents and licenses are exemplifications of property rights. Further, and happily, participation in the U.S. patent system, as patentees and as licensees, is available to citizens and non-citizens alike.[15]

Also, our patent laws do not require the patentee to exploit the patented invention in the United States to be protected from infringement. Foreign nationals as well as U.S. citizens are

free to practice their inventions in foreign countries, subject of course to the patent and other laws of such countries. As a purely protectionist measure, therefore, amendment of our patent laws to extend process invention protection would hardly achieve that purpose. Foreign inventors would equally benefit from the expanded protection of U.S. process patents, and their is also no guarantee that process inventions would be exploited in the United States. What is certain, however, is that the enhanced protection of process inventions can act as an additional insentive for research and developement in the area of process technology.

III. CURRENT PROTECTION OF PROCESS INVENTIONS

A. United States Patent Protection

The general rule for U.S. patents is that the rights conferred to the patentee are confined to the United States and its territories, and therefore claims predicated on acts committed wholly in a foreign country are not cognizable under U.S. patent laws.[16] Accordingly, acts of patent infringement, i.e., the unauthorized making, using, or selling of the patented invention, must occur in the United States.[17] The patentee who's invention is a "manufacture, or composition of matter"[18]- in common parlance, a product - has the exclusive right to exclude others from using or selling the patented product in the United States, regardless of where it was made.

But for the patentee whose invention is a process, the territorial limitation of current U.S. patent law poses an economically significant problem: process patent infringement is limited to unauthorized domestic use of the process, while foreign competitors are free to practice the process invention abroad[19] and then import into the United States the product produced by the patented process. It is also the case that the sale or use of a product of a patented process, even if produced

in the United States, does not constitute infringement.[20] The only act of infringement is the use of the process in the United States; the patentee has no control over the product of the process invention.

B. U.S. International Trade Commission Remedy

Since there is no judicial remedy for patent infringement under current law, the process patent holder's only recourse against importation is an administrative action which claims unfair practice in import trade under section 337 of the Tariff Act of 1930.[21] The International Trade Commission ("ITC") has jurisdiction over enforcement of the statute and is authorized to issue exclusion or cease and desist orders (subject to Presidential disapproval) prohibiting the importation of the designated articles. Although unauthorized importation of a patented product has always been considered an unfair import trade practice under the Tariff Act (of course, any unauthorized sale or use of the product in the U.S. was also patent infringement), importation of goods produced by a patented process was held not to be within the scope of unfair trade under the original version of the Tariff Act.[22] Congress never intended such a result and made itself clear in 1940 by adding section 337(a) expressly bringing the importation of articles produced by a patented process within the coverage of the Tariff Act.[23]

Notwithstanding the fact that the ITC has a true monopoly on the remedy available to process patentees, the Commission has seldom exercised its power to protect process patentees from importation.[24] Since enactment of section 337a in 1940 to 1979, only one court has had occasion to consider an exclusion order issued by the Commission under section 337 that involved the importation of products of a patented process. In that case, In re Von Clemm[25], the court affirmed the Commission's exclusionary

order principally on the basis of product claims and without reference to section 337a in the majority opinion.

Intitiation of an action under section 337 of the Tariff Act requires a private party to file a complaint with the ITC.[26] The essential elements of an unfair trade claim under §337 are (1) importation or sale of articles into the U.S.,(2) "the effect or tendency of which is to destroy or substantially injure an industry," or to prevent the establishment of an industry, (3) said industry is or can be "efficently and economically operated, in the United States."[27]

Much of the current debate over the proposed "process patent" legislation has centered on the adequacy of the ITC remedy. Although the proposed legislation does not dictate a "either/or" decision, product patents having always enjoyed the protection of both the ITC and patent infringement remedies, the need for the patent infringement remedy is even more compelling when the limitations of the current remedy are understood.

Although section 337a brings importation of products produced abroad by a process patented in the United States within the unfair trade practices considered under section 337, infringement of the process patent alone is not a violation. The patentee must also show: that the patented process is being exploited in the United States as part of a domestic industry;[28] that the importation or sale of articles in the United States has the effect or tendency to destroy or substanially injure said industry[29]; and that said industry is or can be efficiently and economically operated[30] in the United States.

These three additional elements of proof, in combination with the establishment of patent infringement and validity, geometrically increase the complexity of the complaintant's task. Now, impose a one year (18 month, in complicated cases) limit on completion of the ITC proceeding and you have added time pressure to complexity.

Having cleared both patent infringement/validity and

antitrust-type economic hurdles in record time, the complaintant must still overcome one more obstacle - the patentee must plead that the desired relief is in the public interest.[31] Goodbye, patent counsel and economist; Hello, Ralph Nader.

If, in spite of all the difficulties, the patentee can establish all of the necessary elements of a section 337 claim, the ITC may issue either an exclusion order or a cease and desist order.

However, the ITC is without authority to award money damages for past infringement. This lack of a damages remedy is one of the major limitations of the ITC action.[32] Frequently, imports may go undetected for a substantial period of time before they are discovered and an ITC action can be intitiated. This lag period may be prolonged, and the unrecoverable monetary damages significant. Also, if importation is discovered late in the term of the patent, the expense of an ITC action may prohibit obtaining even the modest injunctive relief that is available.

Another serious limitation, particularily where trade secrets and process technology are involved, is the circumscribed scope of discovery allowed by foreign countries. Many foreign countries view the scope of United States discovery as intrusive and contrary to public policy. Although the discovery power of the ITC under section 337 was greatly enhanced by the Trade Act of 1974[33], discovery in foreign countries remains more difficult in an administrative proceeding, such an ITC case, than in a judicial proceeding. Many countries have made treaty commitments to the United States to cooperate in judicial proceedings, but they are generally under no such obligation with respect to administrative proceedings and not inclined to allow extensive discovery in ITC proceeding.[34] Extensive use of discovery is of particular importance in proving use of a patented process where the imported product may be manufactured in any number of ways.

In addition to these procedural limitations, the present ITC remedy is useless to a significant number of patentees,

principally those who, for whatever reason, have not used the patented invention in the United States. For example, a individual, a university, or a small business may hold a patent, but be unable to self-exploit the invention or reach agreement with a licensee. If the patent has not been utilized in this country, the patentee cannot show that any industry is destroyed or substantially injured.[35] Consider also the situation where a patentee holds three seperate patents on different processes of producing an antibiotic. Of the three processes, one is marginally more economical, either inheritantly or because fewer modification have to be made to the patentee's manufacturing facilities. The patentee naturally elects to use the more economical process. Because the other two process inventions have not been utilized in this country, the patentee cannot show that their use abroad destroys or substantially injures that industry.

Also, foreign citizens holding U.S. patents and those U.S. citizens who choose to exploit their process inventions abroad, have no recourse under the Tariff Act against unauthorized importation.

The ITC action under section 337 does, however, offer some advantages unavailable in a patent infringement actions that make its retention as an alternative to infringement advisable. The previously mentioned expeditious nature of the administrative proceeding provides the parties with resolution far more rapidly than does a comparable district court action for infringement.[36]

A patentee who seeks immediate protection from importation is more likely to obtain a temporary exclusion order from the ITC, where it is easier to make a showing of "tendency to injure" than it is under the district court standard where "irreparable injury and likelihood of success" must be demonstrated to obtain a preliminary injunction.[37]

With respect to the final exclusion order, the ITC may issue

an exclusion order against a particular importer, or it may issue a general exclusion order against importation of the product of the patented process, regardless of the source and the importer. Under a general exclusion order, a party, even if not involved in the orginal administrative action has the burden of proving that the imported articles were not made by the patented process. Moreover, in this type of advisory opinion proceeding, the importer is not allowed to challenge the validity of the patent or raise any other defense, e.g., patent misuse, that would be available to a defendant in a patent infringement suit.[38]

Finally, in an ITC proceeding, it is unnecessary to produce direct evidence to show how the product was made when expert testimony establishes that the goods "must have been made by the patented process."[39]

C. Foreign Patent Protection of Processes

Rather than rely on U.S. law for protection, the U.S. patent owner can choose to protect itself against foreign competition by securing a patent in those nations where the process is likely to be used. Then, if the patented process is used without authorization in a country where patent protection has been obtained, the patentee can bring an infringement suit in that country's courts, based on its foreign process patent rights.

Although most corporate patentees obtain patent protection in most countries where they anticipate that they will market their invention, the procedure can be very costly[40] Further, patent protection is not always available in many potential manufacturing countries, even if it is, the measure of protection is often inadequate.[41] Moreover, the foreign court proceedings are unpredictable and inconvenient.

D. International Approach to Protection of Process Inventions

Extensive discussion of the various measures of protection

afforded process inventions by the patent laws of our major trading partners is beyond the scope of this paper.[42] It is important, however, to appreciate the types of protection that are offered by the patent laws of our foreign competitors. There are generally three types of patent law protection for process inventions that have been adopted internationally as follows:[43]

> Class I - Importation of product produced by patented process forbidden:
> United Kingdom, Japan, France, Sweden, Norway, Portugal, Iceland, Finland, Denmark, Cyprus, and Canada (by judicial decision).
>
> Class II - Patented Process includes direct product:
> Austria, Cyprus, Denmark, Finland, France, Federal Republic of Germany, Greece, Italy, Japan, Liechtenstein, Netherlands, Norway, San Marino, Spain, Sweden, Switzerland, and the United Kingdom.
>
> Class III - Presumption in favor of process patentee that imported product was made by the patented process:
> West Germany, Greece, Italy, Netherlands, and Switzerland.

The type of protection provided by Classes I and III was the focus of the proposed legislation. The assertion that extended process patented protection would bring U.S. patent law into conformity with the laws of our major trading partners would clearly appear well supported by this list of international protection.

IV. THE IMPORTANCE OF PROCESS INVENTIONS TO THE BIOTECHNOLOGY INDUSTRY

Although the proposed process patent legislation would effect all process inventions regardless of the industry or nationality of the inventor, the impact of the legislation can be better understood by narrowing the focus to a study of one important new U.S. industry - biotechnology.

Biotechnology has been characterized as the last major technological revolution of this century. The United States, as so often in the past, has been in the vanguard of the basic research revolution; but the United States' role, as the industry

undergoes its evolution from innovation to commercial application, has yet to be precisely determined. All too often, our technological superiority has been "short circuited" on the way to the marketplace by other more aggressive and efficient foreign competition.

Given the potential importance of the biotechnology industry to the U.S. industrial competitiveness[44], the relat.vely small collection of U.S. patents issued within this area of technology, and the author's theory that the biotechnology industry, unlike most manufacturing industries, is inherently destined to be - at least initially - process, rather than product oriented,[45] a survey of the industries' patent profiles was conducted to get a quantitative measure of the potential impact of extended process patent protection on the biotechnology industry.

Of the patents in Genetics Engineering - Class 935, fifcy-three percent (53%) would be affected by extented process patent protection.[46] In contrast, in the traditional pharmacuetical industry, thirty-one (31%) of the patents covering "new drugs" approved by the Food and Drug Administration from January 1963 through August 1983 involve process patent claims that would be affected by extended process patent protection.[47]

Statistically, the proposed legislations potential effect on patent protection in the biotechnology industry is significant. But whether the lack of patent protection constitutes a competitive threat depends on the ability of the "free-riders" to profittably use this esoteric process technology abroad.

Generally, the bare disclosure in a patent, absent "know-how," is not sufficient in areas of sophisticated manufacturing technology, e.g., microbiological munipulation, to allow unauthorized competitors to efficiently exploit a process invention. Whether or not foreign competitor in the biotechnology industry will be able to take advantage of the present loophole in U.S. process patent cannot be answered definitively, at this time. However, in the high-profit-margin

pharmacuetical and diagnostic markets, it seems likely that patented biotechnology processes can be used abroad, without detailed "know-how," to produce products that can compete with those produced by the patentees' processes. But in other markets with lower profit margins, e.g., industrial chemicals, pesticides, and veterinary products, exploitation of biotechnology processes, without "know-how," may be so inefficient that no threat to competition is realistic.

Whatever the actual threat to the international competitiveness of the U.S. biotechnology industry might be, it seems imprudent to delay legislative action on enhanced process patent protection until the effect on the industry is readily apparent. Process inventions may be to the biotechnology industry what "silicon chips" are to the semiconductor industry. Although the Semiconductor Chip Protection Act of 1984[48] provided new and much needed protection for "mask works", the legislation may have come too late to help the struggling U.S. semiconductor industry. For the U.S. biotechnology industry the future is being shaped now; enhanced process patent protection at the earliest possible time can only improve its competitive position.

V. PROPOSED CHANGES IN U.S. PATENT PROTECTION OF PROCESSES

During the Second Session of the 98th Congress, three seperate bills that included sections enhancing the protection of patented processes were under consideration in both the House and the Senate.[49] The bills differed in some ways, but their fundemental characteristics are similar. The Administrations bill would amend section 154 of the patent statute to provide a process patent owner with the additional exclusive right to use or sell products made by the process. A corresponding amendment to section 271(a) would be made to include within the scope of infringement the unauthorized use or sale of products made by a

patented process. A new section, §295, would be added creating a presumption in favor of the patentee that the patented process was used in manufacturing a particular product whenever the patentee shows a "substantial likelihood" that the process was used and the patentee has "exhausted" all reasonable means of discovery.

The Administration bill's proposed amendment would provide the patentee with a direct action for patent infringement. Like any other infringement action, damages for past infringement would be available and there would be no need to resort to the economic analysis required by the presently available ITC remedy.

VI. CONCLUSION

The essense of the patent grant is the right to exclude others from profitting by the patented invention.[50] With the current loophole in our patent law, at best, we are impairing the ability of process patent holders to earn their rightful rewards, and, at worst, we are reducing the incentive for other prospective inventors to invest in the creative efforts that produce more efficient ways to produce the goods consumers demand. The erosion of our intellectual property rights by the wave of global competition is seriously undermining the United States traditional leadership position in innovation.

U.S. process patent holders only present protection against importation of goods manufactured abroad, is an administrative action under section 337 of the Tariff Act of 1930. Although the remedy afforded by section 337 has its virtues, on balance it asked too much in the way of proof and procedure and it give too little, principally the lack of available damages. For some process patentees, this remedy, such as it is, is not available at all.

A patent infringement remedy is needed to adequately protect the U.S. process patent holders from the unauthorized use of

their processes abroad. The recently proposed legislation would provide such a remedy and bring our patent laws into conformity with our major world trading partners. To suggest that our patent laws should be given extraterritorial effect is no longer taboo. Congress has recently given extraterritorial effect to patent infringement by prohibiting the supplying of components of a patented invention that are to be assembled outside the United States.[51]

In combination with the section 337 remedy of the ITC action, the proposed process patent infringement remedy would provide protection that would be commensurate with the importance of process technology. For some industries, such as the biotechnology industry, this added protection could be a significant factor in its future international competitiveness.

The concept of extraterritorial protection of U.S. patented processes is an idea whose time has finally come.

FOOTNOTES

[1] Cong. Globe, 32nd Congress, 1st Sess. 1571 (1852)(Statement of Sen. Borland concerning a bill giving "further remedies to patentees," i.e., to make the importation of wooden articles manufactured in any foreign territory adjoining the United States by a process or machine patented in the United States infringement of said patent). Notwithstanding Senator Borland's objections, an amended bill was passed (21 to 15) by the Senate on February 8, 1853. Cong. Globe, 32nd Congress, 2nd Sess. 536 (1853). However, there is no record of the bill ever being reported to the House, and the Congress adjorned on March 3, 1853 without passing the measure into law. In re Amtorg Trading Corp., 22 C.C.P.A. 558, 75 F.2d 826, 24 U.S.P.Q. 315, at 333 (Dissenting opinion of Bland, J.).

[2] The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter or material. 35 U.S.C.A. §100(d)(1985). A process is a mode of treatment of certain materials to produce a given result. It is an act or a series of acts performed on the subject-matter, to be transformed and reduced to a different state of things. Cochrane v. Diemer, 94 U.S. 780, at 788, 24 L.Ed. 1139 (1877).

[3] The term "patentee" is understood to include not only the original inventor, but also any successors in title to the patent such as assignees. See, 35 U.S.C.A. §100(d) (1985).

[4] Senator Borland was well ahead of his time in recognizing the the global competition on the horizon: "I cannot understand fully the propriety of restricting the operation of this law to territories contiguous to the United States.... The

communications between the United States and England especially have been rendered so convenient and speedy, that a patent may be violated in England and introduced across the Atlantic almost as readily as from Canada." Cong. Globe, 32nd Congress, 1st Sess. 1566 (1852).

[5] Numerous countries operate under the principle that a process patent provides rights to the sale and use of the product of the patented process. These countries include Japan, West Germany, The United Kingdom, France, Canada and Italy.

[6] The Report of the President's Commission on Industrial Competitiveness, Global Competition, The New Reality, Vol. I at 20 (1985).

[7] Commercial Biotechnology: An International Analysis, United States Congress, Office of Technology Assessment, at 390 (1983).

[8] H.R. 6286, 98th Cong., 2d Sess. §101 (1984)[hereinafter cited as the "Kastenmeier Bill"]. The bill provides that: "Whoever without authority imports into or sells or uses within the United States a product which is made in another country by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent."

S. 1841, 98th Cong., 1st. Sess. §§501-503 (1983) and H.R. 3878, 98th Cong., 1st Sess. §§501-503 (1983)[hereinafter cited collectively as the "Administration Bill"]. Both the House and the Senate versions are identical. Each provides: "If the patented invention is a process, whoever without authority uses or sells in the United States during the term of the patent therefor a product produced by such process infringes the patent."

H.R. 3577, 98th Cong., 1st Sess. (1983) and S. 1535, 98th Cong., 1st Sess. (1983)[hereinafter cited collectively as the "Mathias/Moorehead Bill"]. Each bill provides: "If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by a such process infringes the patent."

[9] To truly appreciate Senator Borland's distain for the proposed process patent legislation it is necessary to understand just how "special" this legislation was. Not only was the operation of the law restricted to articles made of wood and to importation from countries contiguous with the United States, the object of the bill was to appease a patron patentee - one Mr. Thomas Blanchard.

Mr. Blanchard was the inventor of a machine that revolutionalized the manufacture of wooden shoe lasts and axe handles. Cong. Globe, 32 Congress, 1st Sess. 1569 (1852). For his contribution he had received a patent conferring twenty-eight years of statutory exclusivity (under prior law, a fourteen year initial term and a fourteen year renewal term) and by special act of Congress in 1848 had been granted an additional fourteen year extention - a total of 42 years of protection! Id. at 1571. As Senator Borland remarked: "if any people upon this earth claiming the benefit of exclusive use of their invention, have ever had cause to be satisfied with the legislation of Congress, these very people are the men." Id. Notwithstanding his extraordinary term of patent protection, Mr. Blanchard when faced with the use of his machine in Canada sought "process patent" legislation to give himself extraterritorial protection. Such "chutzpah" or "greed" is unfortunately characteristic of the kind of behavior that has contributed to the legislative and judical hostility toward any extention of the patent "monopoly."

[10] U.S. Const. art. I, §8, cl. 8.

[11] 35 U.S.C.A. §261 (1985).

[12] Connell v. Sears, Roebuck & Co., 722 F.2d 1542 (Fed. Cir. 1983).

[13] Blair, Overview of Licensing and Technology Transfer, 8 N.C.J. Int'l & Com. Reg. 167, at 168 (1983).
[14] Carl Schenck, A.G. v. Nortron Corp., 218 U.S.P.Q. 698, at 701, n. 3 (Fed. Cir. 1983).
[15] Id. at 699.
[16] Dowagiac Mfg. Co. v. Minnesota Moline Plow Co., 235 U.S. 641, at 650 (1915).
[17] 35 U.S.C.A. §271(a) (1985); See also, Dr. Beck & Co. G.M.B.H. v. General Electric Co., 210 F.Supp. 86 (D.C.N.Y. 1962).
[18] 35 U.S.C.A. §101 (1985). (Although sequence is not determinative, it is interesting to note that a "new and useful process" is the first in the list of types of patentable subject matter.)
[19] E.g., in a jurisdiction where patent protection may not be available or realistically enforceable.
[20] Merrill v. Yeomans, 94 U.S. 568 (1876); Welsbach Light Co. v. Union Incandescent Light Co., 101 Fed. 131 (2d Cir. 1900); Kryiak v. Owens Bottle Co., 25 F.2d 358 (N.D. Ill. 1928).
[21] Tariff Act of 1930, §337 and §337(a) (Pub. L. No. 71-361, 46 Stat. 703 (codified as amended at 19 U.S.C.§1337 (1982)).
[22] In re Amtorg Trading Corp., 22 C.C.P.A. 558, 75 F.2d 826, 24 U.S.P.Q. 315 (1935)(Reversing the Tariff Commission and holding that importation into the United States of goods manufactured by a process patented in the United States for which patentees hold no patents in country of origin of goods, and sale of same here was not infringement and therefore could not be characterized as an unfair trade practice under Section 337 of Tariff Act of 1930.)
[23] Pub. L. No. 76-711, 54 Stat. 724 (1940)(codified as amended at 19 U.S.C. §1337(a)(1985)) Section 1337a states:

> The importation for use, sale, or exchange of a product made, produced, processed, or mined under or by means or a process covered by the claims of any unexpired valid United States letters patent, shall have the same status for the purposes of section 1337 of this title as the importation of any product or artivle covered by the claims of any unexpired valid United States letters patent.

It is interesting to compare the original house version of the bill, passed by the House and referred from the House Committee on Mines and Mining, with the final enactment above:

> It shall be deemed an unfair trade practice and a violation of the rights of the patentee, to import for use, sale, or exchange any minerals mined, produced, or processed by use of any mining process covered by the claims of any outstanding United States letters patent heretofore or hereafter issued, except where such minerals are produced, processed, or mined under authority of the owner of such process.[Emphasis added.] H.R. Rep. No. 1781, 76th Cong., 3rd Sess. 1 (1940).

Im sure that Senator Borland would have had a few choice words for this type of "special" legislation.
[24] Note, Importation of Articles Produced by Patented Processes: Unfair Trade Practice or Infringement?, 18 Geo. Wash. J. Int'l L. & Econ. 129, at 134 (1984).
[25] 43 C.C.P.A. 56, 229 F.2d 441 (1955).
[26] 19 C.F.R. §210(a)
[27] 19 U.S.C.A. §1337 (1985).
[28] The ITC has defined "domestic industry" as that portion of the business of the complaintant and its domestic licensees that exploit the patent at the time the complaint is filed. See,

Certain Molded-in Sandwich Panel Inserts and Methods for their Installation, Inv. No. 337-TA-99, 218 U.S.P.Q. 832, at 836 (Int'l Trade Comm'n, 1982).

[29] The "tendency to destroy or substantially injure" a domestic industry may be established by evidence of the ratio of infringing imports to domestic production, import trends, the relative prices of imports and domestic products, foreign capacity, and sales and profits of the domestic industry. Certain Combination Locks, Inv. No. 337-TA-45, 205 U.S.P.Q. 1124, at 1127 (Int'l Trade Comm'n 1979).

[30] "Efficient operation" may be established by submitting evidence that the industry uses fast and efficient machines, skilled labor, and modern production techniques. See, Certain Molded-in Sandwich Panel Inserts and Methods for their Installation, Inv. No. 337-TA-99, 218 U.S.P.Q. 832, at 836 (Int'l Trade Comm'n, 1982).

[31] 19 U.S.C.A. §1337(d) (1985). See, Certain Airtight Cast-Iron Stoves, Inv. No. 337-TA-69, 215 U.S.P.Q. 963, 970 (Int'l Trade Comm'n 1980).

[32] See, e.g., Patent Law Improvement Act: Hearing on S. 1535 and S. 1841 before the Subcomm. on Patents, Copyrights, and Trademarks of the Senate Comm. on the Judicary, 98th Cong., 2nd Sess. 59 (1984) (Prepared Statement of Bernarr R. Pravel, President of the American Intellectual Property Law Association); Id. at 230 (Rebuttal Statement by The Ad Hoc Committee to Improve The Patent Laws in response to the Statement of Alfred B. Engelberg, Patent Counsel - Generic Pharmaceutical Industry Association); and The Report of the President's Commission on Industrial Competitiveness, Global Competition, The New Reality, Vol. II at 316 (1985).

[33] Trade Act of 1974, Pub. L. No. 93-618, 88 Stat. 1973, 2053-56 (1975) (codified as amended at 19 U.S.C. §1337(c)).

[34] Comments of Mr. O'Rielly, of Finnegan, Henderson, Farbow, Garrett and Dunner, Washington, D.C.

[35] H. Blair, Comments on the Statement of Alfred B. Engleberg, Patent Counsel - Generic Pharmacuetical Industry Association before the Senate Committee on Judiciary, Subcommitee on Patents, Trademarks and Copyrights on S. 1535 dated April 3, 1984, at 1 (undated).

[36] Memorandum in Opposition to Extraterritorial Expansion of the Patent Laws, Ad Hoc Committee of Multinational Chemical and Industrial Manufactures, at p. 9. (Obtained from William F. Haddad, President of the Generic Pharmacuetical Industry Association, N.Y., N.Y.)

[37] Id. at 9.

[38] Memorandum from Alice Zalik, Assistant General Counsel, Office of U.S. Trade Representative, to Mike Remington, Chief Counsel, Subcommittee on Courts, Civil Liberties, and the Administration of Justice (August 14, 1984), at p. 3.

[39] In re Von Clemm, 229 F.2d 441, 445 (C.C.P.A. 1955).

[40] Where a machine or method is covered by a number of patents the wide ranging foreign patent coverage can be extremely expensive. At present, it costs approximately $1,000 per invention to file a patent application in foreign countries. Thus, if a piece of equiptment is covered by ten patents, which the inventor wishes to file in twenty countries, the cost is $200,000. That is just the filing costs. See, Blair, supra note 11.

[41] The Report of the President's Commission on Industrial Competitiveness, Global Competition, The New Reality, Vol. I at 24 (1985).

[42] For comparitive analysis of the British versus U.S. protection of process inventions, See, Note, Importation of Articles Produced by Patented Processes: Unfair Trade Practice or Infringement?, 18 Geo. Wash. J. Int'l L. & Econ. 129 (1984).

[43] Addendum to Memorandum from Alice Zalik, Assistant General Counsel, Office of U.S. Trade Representative, to Mike Remington, Chief Counsel, Subcommittee on Courts, Civil Liberties, and the Administration of Justice (August 14, 1984).

[44] It was also intimated to the author that the concern of the generic drug industry with regard to the extention of process patent rights was not primarily over enhanced protection for domestic pharmacuetical manufactures, which generally have patent protection over the product as well as any process. It seems that the generic industries primary concern was over the enhanced protection of biotechnology processes which it believes will play an increasingly important role in the pharmacuetical market within the next five to ten years.

[45] This may be so because the principal and most immediate impact of commercial application of biotechnology is the production of "counterpart" products, such as antibiotics, amino acids, hormones and proteins, by new bioengineered processes that offer either more economical means of production or greater purity. Although these "first generation" or "counterpart" products lack the requisite novelty to qualify for product protection, it is legally clear that the bioengineered microorganisms and the processes by which the products are made comprise patentable subject matter.

[46] The 53% represents 194 of 368 genetic engineering patents. Based on analysis of "Technology Profile Report - Genetic Engineering," The Office of Technology Assessment and Forecast, U.S. Patent and Trademark Office (Data based on patents granted from 1963 through December 1984). The statistical conclusion reached was based on a review of the titles of the patents listed in the Profile Report which included all U.S. patents in Class 935 - Genetic Engineering: Recombinant DNA Technology, Hybrid or Fused Cell Technology and Related Manipulation of Nucletic Acids. If the title indicated that a "process," "method of producing," or "synthesis," was the subject matter of the patent either alone or in combination with a product, it was deemed to be a "process patent" that would be effected by the proposed legislation. The claims of a representative number of these patents where actually reviewed and it was the author's conclusion that the titles were sufficiently accurate for the purposes of this report.

[47] Pharmacuetical Manufacture's Association ("PMA"), Patent Information on New Drugs approved by FDA from January 1963 -August 1983 (Obtained from Edwin C. Mulcahy, Jr., Esq., Associate General Counsel, PMA).

[48] Pub. L. No. 98-620, 98 Stat. 3347 (1984) (codified at 17 U.S.C. §§901-914). The Act establishes a new system for providing ten year exclusive rights in semiconductor chip products; first applications to register mask works could be filed as of January 7, 1985.

[49] The Administration's bill proposed three amendments to the patent statute:

A. Section 154 of title 35, United States Code, is amended by inserting after "invention" the second time it appears the words ", and if the invention is a process of the right to exclude others from using or selling products produced,".[Emphasis added.]

B. Section 271 of title 35 is amended -
   1. by redesignating subsection (a) as paragraph (a)(1); and
   2. by inserting the following new paragraph (a)(2):
      "(a)(2) If the patented invention is a process, whoever without authority uses or sells in the United States during the term of the patent therefor a product produced by such process infringes the patent."[Emphasis added.]

C. Title 35, United States Code, is amended by adding the following new section 295:

1. §295. Presumption: Product Produced by Patented Process.

"In actions alleging infringement of a process patent based on use or sale of a product produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has exhausted all reasonably available means through discovery or otherwise to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so produced, and the burden of establishing that the product was not produced by the process shall be on the party asserting that it was not so produced.". [Emphasis Added]

VI. The Mathias/Moorehead Bill - S. 1535, proposed the following:

A. Section 154 of title 35, United States Code, is amended by inserting after "United States," the following:

"and , if the invention is a process, of the right to exclude others from using or selling products produced there by throughout, or importing products produced therby into the United States,".

B. Section 271 of title 35, United States Code, is amended by -

1. inserting "(1)" after "(a)";
2. adding at the end of subsection (a), the following:

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by a such process infringes the patent."

C. Section 287 of title 35, United States Code, is amended by -

1. adding at the end thereof the following new subsection:

"(b) No damages shall be recovered by the patentee for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process except on proof that such infringer knew of or was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such knowledge or notice. Filing of an action for infringement shall constitute such notice.".

VII. The Kastenmeier Bill, H.R. 6286, proposed the following:

A. Section 271 of title 35, United States Code, is amended by adding at the end thereof the following new subsections:

"Whoever without authority imports into or sells or uses within the United States a product which is made in another country by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the

product occurs during the term of such process patent."

B. Section 287 of title 35, United States Code, is amended by adding at the end thereof the following: "No damages may be recovered for an infringement under section 271(e) of this title unless the infringer was on notice that the product was made by a process patented in the United States.".

[50] Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 696, 65 L.Ed.2d 696, 206 U.S.P.Q. 385, at 404 (1980).

[51] Patent Law Amendments Act of 1984 (H.R. 6286, Pub. L. No. 98-622, codified as 35 U.S.C. §§271(f)(1) and (f)(2)) (Overturns Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 32 L.Ed.2d 273 (1972)).

STATEMENT OF THE
AMERICAN TEXTILE MANUFACTURERS INSTITUTE

BEFORE
SENATE JUDICIARY SUBCOMMITTEE ON
PATENTS, COPYRIGHTS AND TRADEMARKS

OCTOBER 23, 1985

Mr. Chairman, we appreciate the opportunity to submit this statement for the printed record of hearings on process patent legislation, (S.1543).

The American Textile Manufacturers Institute (ATMI), is the central trade association of the American textile industry, representing about 85 percent of the domestic industry for the spinning, weaving, knitting and finishing of wool, cotton, silk and man-made fibers. ATMI provides governmental, economic, international trade, occupational safety and health, statistical, public relations and other services to the industry. This industry represents a major industrial segment of the nation's economy with approximately 700,000 employees which are 47 percent women and 23 percent minorities, both of which are well above the national average for manufacturing.

At the outset, Mr. Chairman, ATMI supports process patent legislation. In the case of a process patent, there is no effective way by which a patentee can prevent a firm from duplicating the protected process overseas and then selling the product of that process in the U.S. Therefore, we need to strengthen our patent system by closing a loophole that affects products manufactured abroad using a U.S. patented process.

The American textile industry is regarded today as the most efficient and modern in the world, and our government must protect the results of our industry's research and development -- the resources which have produced our superior efficiency and high productivity. We cannot afford to allow anticompetitive practices such as patent infringement undermine our industrial base which has substantially eroded as a consequence of import penetration. The very least we can do is prevent foreign manufacturers from using our patented processes without permission to make products for sale in the United States in competition with our own products.

Under current law, the only remedy to prevent goods manufactured in a foreign country by a process protected by a U.S. patent from entering the U.S., is inadequate. Though the Tariff Act of 1930 and the Trade Act of 1974 give the International Trade Commission the general power to exclude imports when the importer engages in unfair trade methods of competition or unfair acts, it is not designed to specifically protect intellectual property rights. A complaining party must show that the imports threaten an efficient and economically operated domestic industry with substantial injury. While the U.S. textile industry is currently experiencing a decline in production as a consequence of foreign import penetration, it would be very difficult to prove injury as a result of patent infringement. ATMI believes that it should be enough that the imported products infringe a patent without having to overcome such obstacles to relief.

We are continuing to rely on patented technology in order to maintain some form of competitive edge over our foreign counterparts. Consequently, we need to ensure this advantage through a protection of our intellectual property.

As we understand, America's major trading partners have provisions similar to S. 1543 in the patent laws of their countries. We believe the U.S. should give its companies the same protection and place U.S. patent law on a par with the patent laws of our competitors. Therefore, we support process patent legislation (S. 1543) and urge its swift passage.

CORRESPONDENCE

AT&T
Bell Laboratories

W. L. Keefauver
Vice President and General Counsel

600 Mountain Avenue
Murray Hill, NJ 07974
Phone (201) 582-2233

October 21, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman, Subcommittee on Patents, Copyrights
and Trademarks
SR-387 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Mathias:

I am pleased to provide on behalf of AT&T these comments on S.1543.

This bill addresses a problem faced by U.S. process patent owners for many years. Unlike most of its important trading partners, the U.S. has not availed itself of the provision of Article 5 quater of the Paris Convention. Therefore, a U.S. process patent owner has no remedy if products made abroad by the patented process are imported. This not only encourages the movement of jobs to countries where process patent protection is not available, but also undermines the value of the intellectual property resulting from very expensive research and development. Quite obviously, neither of these benefits the United States public.

Although this problem is usually associated with process intensive industries such as chemicals and pharmaceuticals, it poses a potential problem for AT&T as well. For example, AT&T's patented processes for making semiconductor integrated circuits and optical fibers are currently very important to its business. Further, it seems likely that process technologies will become of increasing importance as international competitiveness pressures all of U.S. industry to achieve high quality manufacture with low unit cost.

S. 1543 would help remedy this problem by making the importation, use or sale of products manufactured abroad by a patented process an infringement of that patent. We strongly endorse this remedy.

The bill, however, goes beyond its statement of purpose and applies to domestically manufactured products as well as to those manufactured abroad. Since domestic manufacturers are subject to the jurisdiction of the Federal Courts, the holder of a U.S. process patent has a remedy under current law. The englargement of the class of potential defendants to users as well as to all levels of distribution is therefore not necessary to ensure enforcement of U.S. process patent rights in the case of domestic manufacture. Instead, it seems likely only to increase litigation costs.

I am aware of opinion that to permit enforcement of process patents against distributors and users of resulting products only if manufactured abroad might violate U.S. GATT commitments. This does not seem obvious to me and I would urge the Committee to limit the bill to the known problem relating to foreign manufacture unless our treaty commitments clearly compel us to do otherwise.

Ian M. Ross, President of AT&T Bell Laboratories was a member of the President's Commission on Industrial Competitiveness and served as co-chairman of its Research, Development and Manufacturing Committee. That Committee and the Commission made the strengthening of intellectual property rights a high priority for the United States and issued a detailed report with specific recommendations. The problem addressed by S.1543 was one of those identified in that report.

I applaud your initiative, along with that of your co-sponsors, in seeking to strengthen the effectiveness of the U.S. patent system.

Very truly yours,

W. L. Keefauver
Vice President and General Counsel

National Association
of Manufacturers

Lee Hamilton
Senior Vice President

October 23, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman
Subcommittee on Patents, Copyrights
and Trademarks
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Mathias:

The NAM would like to endorse S. 1543, the Patents Protection bill, introduced by you and Senator Lautenberg. The NAM strongly supports this legislation as a means of protecting U.S. owners of patented processes from infringement by foreign manufacturers.

In a new policy statement, recently adopted by the NAM Board of Directors, we call for a strengthening of U.S. intellectual property laws to increase the system's overall protection. In particular, our policy urges that holders of U.S. process patents should be protected from infringement caused by the sale or use in the U.S. of goods manufactured abroad by an infringing process.

Our policy further notes that "Most countries' intellectual property laws are based on the principle that foreign inventors are afforded an equivalent level of protection as domestic inventors. This principle has often failed to ensure sufficient protection because of the total absence of laws. Ultimately, adequate international protection rests with the effective enforcement of strong domestic intellectual property laws by individual countries."

We believe that passage of S. 1543 would go a long way to affording the protection of U.S. process patents that is so urgently needed.

We would greatly appreciate it if these views could be made as part of the record of your hearings October 23, 1985, on this legislation.

Sincerely,

Lee Hamilton

NAPM

National Association of Pharmaceutical Manufacturers

747 Third Avenue, New York, New York 10017 • (212) 838-3720

NILES BARRY
PRESIDENT
•
MILTON A. BASS
GENERAL COUNSEL
•
GEORGE SCHWARTZ
EXECUTIVE DIRECTOR

November 12, 1985

The Hon. Senator Strom Thurmond
Chairman
Senate Committee on the Judiciary, SD-224
The Capitol
Washington, D.C. 20510

Re: S. 1543 [Process Patent Amendment of 1985]

Dear Mr. Chairman:

The National Association of Pharmaceutical Manufacturers ("NAPM") respectfully submits its comments in opposition to proposed Senate Bill S. 1543. NAPM believes, for the reasons stated below, that enactment of this bill in its present form would seriously injure domestic generic drug manufacturers and distributors and raise the cost of pharmaceuticals to the American consumer.

NAPM is a national trade association representing more than 100 manufacturers and distributors of multi-source prescription and over-the-counter drug products, veterinary drugs, vitamins and other dietary supplements. Since 1955, NAPM has been the leading voice for what is commonly known as the generic drug industry. In this capacity, NAPM has frequently appeared in hearings before Congress and state legislatures. NAPM has also appeared before administrative tribunals, has regularly participated in U.S. Food and Drug Administration ("FDA") rulemaking procedures, and has participated in the judicial forum as a party and as amicus curiae. NAPM has sponsored educational seminars, bringing together representatives of the pharmaceutical industry with the scientific and legal community, as well as officials of FDA and the Drug Enforcement Administration. NAPM has also made a significant contribution in the development of the solid dosage form identification system for over 600 drugs.

The proposed Senate bill would give unprecedented protection to process patents and would result in unfairly extending the patent life of pharmaceutical products thereby insulating these important drugs from domestic competition.

At the present time, finished pharmaceutical products are subject to a minimum of 17 years of patent protection. In addition, the newly enacted Drug Price Competition Act of 1984 extends the years of patent protection to compensate for the "regulatory review period"—i.e., the time period in which FDA reviews and approves a new drug product. Generic competitors cannot manufacture and sell the product in competition

with the so-called pioneer or brand-name manufacturer until the patent for the drug has expired. As is now well known, the existence of competition causes the price of the drug product to be drastically reduced thereby affording consumers savings of millions of dollars. As FDA recently noted in approving the first generic drug products for Valium^{R} on September 4, 1985, generic competition "can save consumers perhaps half a billion dollars to a billion dollars a year."

The proposed bill will have a significant chilling effect upon domestic generic drug manufacturers. Foreign suppliers, for obvious reasons, are not willing to disclose their secret methods of production to third parties. Domestic drug manufacturers therefore rely on the certifications of foreign suppliers that an infringing process is not used in the production of ingredients. However, under the bill's present wording, if a suit is filed claiming infringement of a process patent, the domestic manufacturer must proceed at its own risk because the proposed statute deems the filing of a suit as notice and knowledge to the "infringer" (and presumably "contributory infringers") that a patent has been infringed, thereby subjecting such parties to monetary damages. In all likelihood, the domestic drug manufacturer, who does not have knowledge of the exact process utilized by the foreign supplier, must discontinue manufacture of the product in advance of a finding of infringement or be liable for damages in the event of such a finding. The result is a disruption, if not termination, of competition in the pharmaceutical industry until the process patent expires, which is, in many instances, far in excess of the expiration date for the underlying product patent. Such a burden on commerce would be contrary to the aims of the Administration, Congress, the Drug Price Competition Act, and the fifty states to provide effective generic competition.

Under the present law, companies which are adversely affected by unfair competiton in foreign countries can apply to the International Trade Commission for an import block order upon a showing of substantial injury. See 19 U.S.C. §1337. Such remedy is more than adequate to protect patent owners from importation into the United States of goods made overseas by use of a United States patent process. Enactment of S. 1543 can result in a deprivation of legitimate sources of supply to generic drug sellers and a decrease in price competiton in the United States by unfairly extending drug patent monopolies after the underlying product patent expires. Accordingly, NAPM believes that S. 1543 should not be enacted into law.

Respectfully submitted,

Milton A. Bass
General Counsel

George Schwartz
Executive Director

CATERPILLAR TRACTOR CO.

Peoria, Illinois 61629-6490

November 14, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman, Judiciary Subcommittee on
Patents, Copyrights & Trademarks
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Caterpillar Tractor Co., a manufacturer of construction equipment and diesel and turbine engines, supports enactment of S.1543, process patent litigation.

We understand that your subcommittee has agreed to receive additional comments and, because of our interest in this subject, Caterpillar therefore requests that the attached statement supporting S.1563 be included as part of the hearing record.

Very truly yours,

W. S. Thompson, Manager
Patent Department

WST:en
Telephone (309) 675-4452

Statement for the Record by Caterpillar Tractor Co.
Submitted to
Senate Judiciary Committee
Subcommittee on Patents, Copyrights & Trademarks
re:
Process Patent Legislation (S.1543)
November 13, 1985

Caterpillar Tractor Co., a manufacturer of earthmoving and materials handling equipment, diesel, natural gas and turbine engines, supports the passage of S.1543 Process Patent legislation.

In the construction equipment industry, product innovations of sweeping magnitude are relatively infrequent. And while we need to encourage greater product innovation, the major gains in cost competitiveness and increased productivity will come through developments in process innovation.

Considerable investment is already under way in a wide array of [illegible]mated process techniques through the application of robotics, microprocessors, advanced software and the like. However, a loophole in existing U.S. patent law places these investments in jeopardy. Today there is no effective way to prevent a company from duplicating and using a U.S.-developed process overseas and then selling the product of that process in the United States.

It is not feasible, if one wants to protect the U.S. market, to obtain process patent protection in every country of the world. Not every country has a patent system and some pointedly deny process protection in selected fields. Caterpillar is a leader in the development of specialized metallurgical compositions and processes best suited for its line of products. Yet Mexico, for example, has a provision in their patent law specifically excluding protection for metallurgical processes. Other countries do not afford protection to manufacturing processes using a computer program as a step in the process while in the U.S. such protection is possible. Some countries seriously dilute the effective enforceability of patent rights by imposing compulsory license provisions if the process is not actually worked in their

country. Thus, under present law there is simply no way to prohibit a foreign based manufacturer from using a process developed and patented by Caterpillar in the United States and selling the product back into the U.S. market in direct competition with Caterpillar-built machines. If S.1543 were enacted into law, the sale of foreign produced product in the U.S. would constitute a patent infringement, and U.S. manufacturers would have available to them effective patent law protection.

On a related point, we also believe that once the plaintiff has satisfactorily demonstrated the probability of a patent infringement, the burden of proof should shift to the defendant to demonstrate that a noninfringing process was used. This is particularly necessary in the case of foreign discovery as many countries have erected protective barriers against the U.S. judicial discovery process. While information provided during the routine judicial discovery process may be of a proprietary nature, we believe the courts can effectively deal with this concern through the use of a protective order. In our opinion, foreign manufacturers who are given access to U.S. markets should assume some obligation to demonstrate compliance with our laws.

The development of new process technologies is key to the survival of many of our established industries. The enactment of process patent protection legislation is essential if our industries are to become competitive, cost effective players in the international marketplace.

THE DOW CHEMICAL COMPANY

OFFICE OF PATENT COUNSEL

November 14, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman, Judiciary Subcommittee on
Patents, Copyrights & Trademarks
United States Senate
Washington, D.C. 20510

Re: S.1543 "Process Patent Bill"

Dear Senator Mathias:

I was pleased your Subcommittee on Patents, Copyrights and Trademarks held a hearing on the above bill on October 23, 1985. Hopefully the overwhelming support for the bill will be taken as indicative of the worth of this piece of legislation.

Many reasons why this bill is in the best interest of the U.S. were aired at the hearing. To me, it boils down simply to putting the U.S. on equal footing with our industrialized foreign country competitors.

What opposition there was to the bill was directed primarily to the emotional argument of costing elderly people more for drug products. These arguments, it seems, fail for want of knowing the real marketplace. We live in a fiercely competitive world. In order to exist in that world, process research is essential and is done principally for two reasons. One is to make products more efficiently and therefore cheaper in order to offer products at lower competitive prices and still make a profit. The second is to make higher quality products with less impurities which makes for better and more effective products for the customer's use, and which minimizes damage to the environment.

Moreover, it should be noted that the other industrialized countries (U.S. competitors), which for the most part lean to socialized medicine, have in place laws equivalent to S.1543. There is no movement in those countries to repeal those laws.

S.1543 would help assure a fair return for the investor in process research in the United States, and would help assure that the United States innovation system can hold its own in the world at large.

I sincerely hope your Subcommittee will endorse this bill and encourage the full Judiciary Committee to favorably act on it.

Sincerely,

Richard G. Waterman

Richard G. Waterman
General Patent Counsel

Post Office Box 1967, Midland, Michigan 48641-1967, U.S.A.
Office: 1776 Bldg. Pruitt Research Center, Washington St., Midland, Michigan 48640

Telex: (023)-227-455 - PATENT
Facsimile Ph: (517)-636-3237
CCITT 2 and 3 (Group 1 -- U.S.A. only)

Cable: DOWCHEMCO - PATENT
(Voice Contact: (517)-636-2213)
Automatic 24 hours

55-522 O - 86 - 10

University of Rhode Island, Kingston, RI 02881
Division of Development and Alumni Affairs
21 Davis Hall 401-792-2291

November 15, 1985

The Honorable Charles Mc C. Mathias
Senate Russell Office Building
Washington, DC 20510

Dear Senator Mathias:

We have been following with some interest your efforts on process patent legislation (S. 1543) and wish to be recorded as supporting this important initiative. My request is that this letter be made part of the record of the hearings you held on October 23.

I am writing to you as chairman of the University's Intellectual Property (Patent) Committee. Because of changes in federal law and policy, colleges and universities have taken a renewed interest in the patenting process. Many of us have major research efforts which produce new technology of value to business and industry. Research efforts here are funded at the $28 million level annually and we are seeing an increasing number of patent applications come forward, a number of them dealing with processes.

While faculty have a responsibility and obligation to initiate the patent application, it is important that financial incentives also be built into the system. As you know, the procedures for obtaining patents are expensive, complex and sometimes tedious for the inventors involved, so the University must be able to protect itself and the faculty member's interests once the patent is issued. When foreign competitors can use our process patents and then bring goods into the country without penalty or controls, this hurts everyone involved. Therefore, we enthusiastically support your efforts.

I have also written to Senators Chafee and Pell of Rhode Island and expect they will support this legislation. In addition, I have discussed this issue with several people in industry and they share our concerns about trying to plug this loophole in our laws.

Sincerely,

James W. Leslie
Vice President

/dh

cc: President Edward D. Eddy

Stauffer Chemical Company
Westport, Connecticut 06881 / Tel. (203) 222-3000 / Cable "Staufchem"

November 18, 1985

The Honorable Charles Mac. Mathias, Jr.
Chairman
Subcommittee on Patents, Copyrights
and Trademarks
Committee on the Judiciary
SD-137 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Mathias:

We would like to submit the following comments into the hearing record on the process patents bill, S. 1543.

Stauffer Chemical Company strongly supports this legislation which would correct flaws in the process patents area. We commend you for your understanding of this problem and your efforts in trying to gain a resolution.

We do have one area of concern to call to your attention. This involves the so-called "grandfather clause" which we do not believe will provide the protection it purports to effect. In our opinion, such a clause will only serve to gut the proposed process legislation to the primary gain of companies in countries foreign to the United States. This will enable such companies to continue to benefit from the results of U.S. research for many years to come. Any possible benefit to domestic generic companies must be de minimis in comparison to the potential loss of protection of U.S. technology and jobs to foreign companies. We would prefer to see this section of the bill removed.

Thank you for the opportunity to submit these comments.

Sincerely,

Robert C. Sullivan
Director
Patent Department

RCS/rj

University Patents, Inc.

November 18, 1985

The Honorable Frank R. Lautenberg
717 Senator Hart Office Building
Washington, D. C. 20510

The Honorable Charles McC. Mathias, Jr.
387 Senator Russell Office Building
Washington, D. C. 20510

Dear Senators:

First permit me to introduce myself. I am president of University Patents, Inc., a corporation which is the exclusive technology transfer representative for a number of American universities, including Princeton University, New York University and the Universities of Pennsylvania, Arizona, Colorado, and Illinois. Not only do we move university-generated technology into industry (our licensees include IBM for electronics, Becton-Dickinson for assay kits, Applied Biosystems, Inc. for genetic engineering, to name a few) but as a result of our activities, millions of dollars have been returned to the universities and used to support further research.

While I applaud your process patent bill (S-1543), I urge you to consider making even further progress.

Within the past ten years, serious inroads have been made in our ability to out produce our economic rivals. Now, for the first time, even our lead in basic technology is being challenged. We now find, not only increasingly greater innovative challenges from countries like Japan and Germany, but find those same countries purchasing technology, stealing technology (recall the Hitachi-IBM situation) or infringing our U. S. patents with impunity.

The reason is simple. We have a patent system under which patent infringement, not patent respect, has been by far the most economically successful route.

First, a patent owner of an infringed patent, if lucky, gets a decision on his "presumptively valid" patent some five years after the enforcement of his rights commences. Thus, his suit against an infringer need not be treated as a contingency in the infringer's current budget, and possibly not even in its five-year plan.

Second, preliminary injunctive relief is non-existent. A non-litigated patent never (that I can find) receives preliminary relief.

1465 Post Road East • P.O. Box 901 • Westport, CT 06881 (203) 255-6044 Telex 501985

Third, when the patentee finally does prevail, he is usually held to "a reasonable royalty" by law. The law says that "reasonable" is the license fee that the patentee has been charging others. Thus, the infringer's worst case essentially becomes his best case. Even interest on past due royalties, which only recently became available due to a Supreme Court decision, is charged only at the going rate.

Now, let us examine the high technology countries of Germany and Japan. These countries have criminal sanctions applying to infringement of their own patents. In Germany, infringement is subject to fine or imprisonment. In Japan, infringement is subject to fine or imprisonment up to five years. These countries truly understand the value of technology. Nor are they alone. Austria, Finland, Greece, Italy, Netherlands and a host of other countries have similar sanctions.

The time has come, while we are still a technology leader, to put teeth into our patent system. The answer is a bill directed to less discretionary and more mandatory Preliminary Relief. Engraved as a hallmark in court houses around the country is the premise:

"Justice delayed is Justice denied".

It is a fact of life peculiar to patents, that open and notorious infringement can spell a patent's death knell. Without preliminary relief, we have the effect of compulsory licensing, a remedy without constitutional, statutory or other legal basis. This effectively renders moot the statutory presumption of validity of our duly issued United States patents.

As a beginning, I enclose a proposed modification to Title 35 United States Code. As one knowledgeable in this field, I stand ready to aid you in any way that I can and would be pleased to meet with you or your staff members at any time.

Sincerely yours,

A. SIDNEY ALPERT, ESQ
President

ASA:lj
Enclosures
cc: Senate Judiciary Committee
The Hon. Lowell P. Weicker, Jr.
The Hon. Christopher J. Dodd

35 USC 283. INJUNCTION (AMENDED)

The several courts having jurisdiction of cases under this title shall grant injunctions to prevent the violation of any right secured by patent, in accordance with the following principles:

(1) at any time after the filing of an infringement action pursuant to 35 USC 281, and if the patent in suit has previously been litigated in a district court and not been found to be invalid or unenforceable under 35 USC 282, the patentee or party claiming under such patentee (hereinafter "patentee") shall be entitled to a preliminary injunction against the adverse party effective until such time as the court in the instant action renders its decision;

(2) upon the filing of an infringement action pursuant to 35 USC 281 with respect to a patent that has not been previously litigated in a district court, the patentee shall be entitled to a hearing regarding a preliminary injunction against the adverse party and the court in the instant action shall grant such preliminary injunction against the adverse party unless such party adequately shows that the patent in suit is likely to be held invalid, non-infringed or unenforceable under 35 USC 282;

(3) upon the finding of infringement of a patent pursuant to 35 USC 271 by a court in a civil action under 35 USC 281, and if such court did not find such patent invalid or unenforceable under 35USC 283, the patentee shall be entitled to a permanent injunction against the adverse party in such suit including, without limitation, any non-party that provides monetary support of such adverse party.

Leroy G. Sinn
Attorney at Law
Patents, Trademarks, Copyrights & Licensing

CONSULTANT—Intellectual Property

P.O. Box 559
Oldwick, NJ 08858
(201) 439-3551

Indiana Office
981 S. 500 East
Kouts, IN 46347
(219) 766-3441

November 19, 1985

The Honorable Charles McC. Mathias, Jr.
United States Senate
Washington, DC 20510

Dear Senator Mathias:

This letter is sent in support of the Senate Bill S.1543 called the "Process Patent Amendment of 1985". I feel that it is highly important and only logical that the U.S. Patent Law be so amended that to import into or to use or sell in the U.S. a product made outside the U.S. using a process patented in the U.S. will be a violation of U.S. Patent Law. In my view this is only fair since most other countries provide the same protection for process patents issued in their countries.

A few years ago, my company had a plant in The Netherlands. In the plant, a process for making a plastic was carried out. It would have been a violation of an unexpired German patent covering the process at the time to export into Germany even though there was no patent in Germany covering the plastic itself. The company accordingly did not export into Germany until the term of that process patent expired.

It is extremely important for this country to encourage invention and innovation in the area of manufacturing processes in order to have the productivities to remain competitive on the world market and even in our own country.

I urge passage of Senate Bill S.1543 and thank you for your consideration.

Very truly yours,

Leroy G. Sinn

Leroy G. Sinn

LGS/oak

SOHIO THE STANDARD OIL COMPANY
1001 TWENTY-SECOND STREET N.W., SUITE 600
WASHINGTON, D.C. 20037
TELEPHONE (202) 785-4888

November 20, 1985

The Honorable Charles McC. Mathias, Jr.
387 Senate Russell Office Building
Washington, D. C. 20510

Dear Senator Mathias:

Standard Oil Company (Ohio) strongly supports current congressional efforts to enact new process patent protection legislation and we welcome the opportunity to submit written comments for the record on S.1453. We urge that S.1453 be changed in two important ways as described below:

1. Assistant Attorney General Douglas Ginsburg testified that the bill should contain language for a rebuttable presumption in infringement cases so that any product that "could have been made by use of a patented process was in fact so made..." It would be up to the defendant to overcome this presumption. Sohio supports such a rebuttable presumption, and notes for the record that several major countries include such provisions in their patent code, in particular the Japanese patent law currently contains such a presumption to fully protect Japanese patent holders. Section 104 of the Japanese Patent Law reads, in essence:

> "In the case of a patent for an invention of a process of manufacturing a product,...any identical product shall be presumed to have been manufactured by that process."

Similar protections need to be provided to U.S. process patent holders, and we therefore urge support for corrective legislation on this matter.

2. Sohio also endorses elimination of the provision that would "grandfather" any patent infringement which began prior to enactment of the legislation. This language would only serve to perpetuate the use of what is essentially a loophole in existing patent law.

We would like to formally request that the above two comments and the attached testmony of Jonathan W. Hinton, Vice President and General Manager, Structural Ceramics Division, Sohio Engineered Materials Company, presented on August 22, 1985, before the Subcommittee on Economic Goals and Intergovernmental Policy of the Joint Economic Committee be included in the record for the Senate Subcommittee on Patents, Copyrights and Trademarks hearing held on October 23, 1985.

Sincerely,

David Litvin

David A. Litvin
Assistant Director
Federal Government Affairs

DAL/jsd

Enclosure

TESTIMONY OF

JOHNATHAN W. HINTON
VICE PRESIDENT AND GENERAL MANAGER
STRUCTURAL CERAMICS DIVISION
SOHIO ENGINEERED MATERIALS COMPANY

BEFORE THE
SUBCOMMITTEE ON ECONOMIC GOALS AND
INTERGOVERNMENTAL POLICY
OF THE
JOINT ECONOMIC COMMITTEE
ON
THE CASE OF JAPAN: BARRIERS TO U.S. EXPORTS

AUGUST 22, 1985

Senator D'Amato:

My name is Jonathan Hinton. I am Vice President & General Manager, Structural Ceramics Division, Sohio Engineered Materials Company. We are an operating division of The Standard Oil Company of Ohio. With me this afternoon are Lewis Koppel, who serves as Director, Strategy Development, Sohio Engineered Materials Company, and R. Lawrence Sahr, Senior Patent Attorney for Sohio. I would like to summarize my remarks and I request that my full statement, which will be sent to your Washington office this week, also be included in the hearing record.

Sohio Engineered Materials Company is headquartered in Niagara Falls, NY and employs nearly 1200 people in New York State. Our most exciting new industrial product is a patented advanced ceramic material which is extremely hard, strong, corrosion, abrasion, and heat resistant. It has many applications for machinery components in severe environments, where even exotic metal alloys cannot do the job.

We appreciate this opportunity to appear before you today. Our Company has had extensive experience with direct investments in Japan.

We have been partners with various Japanese firms going back as far as the 1950's. Our experience there has taught us that there are a great many areas in which Japanese practices make it difficult for U.S. companies to succeed. Today, I would like to focus on one critical area of difficulty, namely patents.

As generally covered by Mr. Mu's and Mr. Suwinski's testimony, commerce in Japan is quite unique. Personal and corporate relationships are so strong that a Japanese firm will purchase from another Japanese firm rather than buy a less expensive equivalent product from an American firm. In addition, Japanese firms have a proven track record of copying the inventions of others. The Japanese patent system should be one of the tools which an American firm can use to minimize the inherent disadvantage we have in attempting to penetrate the complex Japanese market. Unfortunately, it isn't.

Both the U.S. and Japanese Constitutions support, in similar language, the rights of inventors to patents. Society strikes a bargain. In exchange for inventors' placing their inventions into the public domain to advance the state of technology, the government grants the inventor a monopoly for a limited time. This gives society the benefit of advanced technology upon which even newer technology can be developed, while providing the opportunity for the inventors to enjoy the financial rewards of their work.

This bargain works in the U.S. -- for both U.S. and foreign inventors -- because the U.S. patent system is set up in a way that protects the rights of all patentees equally. In Japan, this simply is not so. The practices of the Japanese patent system, industry and society operate to keep foreign inventors from participating equally with Japanese firms in the bargain.

The beginning of the patent process in Japan is to file an application in the Japanese Patent Office. From that point, it generally takes five (5) to seven (7) years for the application to be declared allowable, compared to two (2) to three (3) years in the U.S. Unlike U.S. patent applications, Japanese patent applications are published after 18 months, allowing competitors several years to study and copy new inventions.

The difficulties experienced by U.S. businesses in this initial stage of filing and prosecution of Japanese patent applications have been well documented. Both the American Chamber of Commerce in Japan and the U.S. Embassy, as well as several professional patent associations, have lodged multiple protests with the Japanese regarding these problems. The response has generally been limited to actions designed to publicly placate, without resulting in any significant changes. To use your earlier analogy, Senator, "the undisciplined child has apologized -- but still has neither walked the dog or taken out the garbage."

But what happens next? Once a patent application is found to be allowable, after this 5 to 7 year period, it is republished for opposition. Japanese opposers, who can be anyone from a corporation to a person with no economic interest, have three (3) months from the date of publication to file their oppositions arguing why the patent application should not become a granted patent. We have had extensive experience with this opposition process, which we would like to share with you.

To begin with, there are several unfair, but ultimately surmountable, procedures in the opposition process. The opposition documents are not required to be served by the opposers on the

applicant. They are merely filed in the Patent Office which, in turn, immediately sends those opposition documents, plus patent application files, into what is termed "processing." This bureaucratic processing can take anywhere from one (1) to six (6) months depending upon the number of oppositions filed and the overall workload of the Patent Office. However, during this period, all of these opposition documents, which are, in the words of the Japanese law, "public records available to the public" are not in fact available to the public or the applicant. The applicant does not know the basis for any of the oppositions. He does not even know how many opposers there are or their names.

When the "processing" is completed, the opposition documents are formally served on the applicant's patent attorney. From that date, the applicant has three (3) months -- including the time needed for translation -- to reply to all of the oppositions.

It has been our experience, as well as that of other U.S. firms, that the arguments of the opposition documents are very well thought through and polished. We have been told by Japanese patent attorneys that this is no accident: the opposers have had access to the Patent Office application files since the original publication of the application, in most cases from five (5) to seven (7) years before publication for opposition. Thus, the opposers have had many years to develop their arguments and polish them.

If the patent application technology covers a basic invention, or is considered significant to an important Japanese market, or falls into an area of technology targeted by MITI (the Japanese Ministry of International Trade & Industry) -- such as advanced ceramics -- there will be a surprisingly large number of oppositions. In most of these

cases there will be more than ten (10) oppositions and in a few recent cases, in excess of one hundred (100) -- all of which must be effectively answered in three months. Each opposition brief will contain several reasons why the opposer believes the patent should not be issued. If the applicant fails adequately to answer only one of these arguments, in only one of these briefs -- he loses his patent.

Some of the arguments in some of the briefs will be identical -- not merely similar, but exactly and literally identical. The applicant will notice, if there are many opposers, that certain phraseology is repeated in several of the opposition briefs, each of which has supposedly been developed by a separate and independent opposer. The arguments used and the order of their arrangement will also be repeated in several opposition briefs. In addition, certain support documents are used by all or a majority of the opposers, and those support documents will bear duplicated tell-tale markings, such as photocopy machine imperfections, marginal notes and underlining, indicating that each was copied from a single master copy. It appears that all of the opposers have met to collectively define the issues, distribute the support documents, develop the arguments and divide those issues and arguments among themselves, all by way of mutual agreement. In fact, this collusion is exactly what has happened, as has been verified privately by many Japanese patent attorneys who have attended such meetings. Yet, those same attorneys do not report engaging in such meetings where the applicant is Japanese.

After the applicant files his reply briefs, each opposer may request rebuttal. The Patent Office frequently allows opposers to file rebuttals where the applicant is foreign, especially if there are a large number of opposers or if the arguments and issues are complex. The Patent Office usually takes one (1) or two (2) years to decide to

allow the rebuttals. After it does so, there is no set time limit to file those rebuttals. The applicant, on the other hand, has only forty (40) days to respond to the rebuttals after another bout of bureaucratic "processing" in the Patent Office, as mentioned before. Beyond this, the Patent Office can then decide to allow yet another round of opposer rebuttals, necessitating further responses by the applicant. Finally, if the applicant is successful in persuading the Patent Office that he still has a patentable invention in spite of the oppositions, the Patent Office will issue a decision to grant a patent.

Having survived this ordeal, however, the U.S. firm still does not have an enforceable patent. There are problems that follow the opposition process which go beyond being merely "unfair." Once the patent is actually granted, it can be subjected to a revocation proceeding. Statistics show that a very high percentage of opposed and appealed patent applications, which finally result in granted patents, are subjected to revocation proceedings. Anyone can file a revocation proceeding. A revocation proceeding can be filed even though no oppositions were filed. And, finally, there is no time limitation for the filing of a revocation proceeding; it can even be used as a defense to an infringement suit. The revocation proceeding starts in the Patent Office and, for all intents and purposes, follows the same procedure, and takes the same amount of time as an opposition proceeding. The revocation proceeding is also subject to a two-tiered appellate procedure, taking about two (2) years for each appeal. The net result is a patent which may never reach an enforceable stage.

The terms of a Japanese patent cannot extend for more than twenty (20) years from the date of original filing of the application. The initial application, you will recall, takes between five (5) and seven

(7) years. This leaves a potential useful patent life of between thirteen (13) to fifteen (15) years, provided no oppositions are filed. If oppositions are filed, as much as five (5) more years can be cut from the life of that patent, leaving a potential life of only from eight (8) to ten (10) years. An additional nine (9) years can be cut from the life of the granted patent through revocation proceedings. This means that the possible twenty (20) year patent term can expire before a U.S. applicant has an enforceable Japanese patent.

Thus, the Japanese government has established a system which can be manipulated to ensure that an enforceable patent will never be issued to a U.S. firm until the patent period has expired. U.S. firms have, of course, complained to the Japanese government. The response of the Japanese Patent Office is that an applicant can assert his patent against an infringer by filing suit as of the date that the patent application is published for opposition. A review of those patent infringement law suits filed in the Tokyo District Court, from 1975 to 1985, where the suit was filed under an opposed patent application and/or a granted patent which was subjected to a revocation proceeding, has shown, in every single instance, that the litigation was stayed until all of the oppositions, revocation proceedings and their respective appeals were completely and finally exhausted. Not a single instance was found where a prohibitive order was issued by the Tokyo District Court, to prevent the infringing practice from continuing during the oppositions, revocation proceedings and their respective appeals. Thus, the right to file a patent infringement action, based on a patent application published for opposition, seems to be a hollow right.

The net result of these provisions of the Japanese patent system

is that the Japanese are provided with all of the tools necessary to deny the foreign applicant any effective patent rights in Japan. The use of these tools, in combination with the collusion among interested domestic competitors, can and in many cases, does effectively destroy the exclusive rights that a U.S. inventor otherwise should have under Japanese patent law, and which a Japanese inventor does have in the U.S.

Without a level playing field for patent rights, Japanese industry can continue to blatantly copy the newest U.S. products and, through industry collusion, keep the U.S. patent holder from selling any of his products in Japan. This costs U.S. workers more than just production jobs. Profits from sales to the large Japanese market for advanced ceramics, for example, could be a major source of funding for our R&D efforts in Niagara Falls.

The availability of Japanese-made copies not only prevents U.S. firms from penetrating the Japanese market, but the copies also are shipped to the United States where they compete directly with the U.S. patent holder's products. In cases where the Japanese export products infringing U.S. product patents, U.S. law permits the U.S. patent holder to sue the Japanese firm and force it to stop exporting. However, if the Japanese firm exports products which infringe only U.S. process patents, then U.S. law does not authorize the U.S. process patent holder to force the Japanese firm to stop.

Unlike U.S. law, Japanese patent law fully protects Japanese process patent holders. Section 104 of the Japanese Patent Law reads, in essence:

"In the case of a patent for an invention of a process of

manufacturing a product, ... any identical product shall be presumed to have been manufactured by that process."

Similar protection must be provided to U.S. process patent holders. We urge your support for corrective legislation in the Senate this Congress.

We are currently engaged in litigation with a major Japanese ceramics company, Kyocera, to stop them from selling infringing products in the U.S. Kyocera's Director of Research & Development has publicly admitted in a newspaper interview that Kyocera has infringed our U.S. patents. But, such litigation is both time consuming (5 years, so far) and costly, robbing precious resources for our Niagara Falls-based activities. Counterparts to these U.S. patents are still pending in Japan because they are mired in opposition proceedings. And all the while, Japanese customers which should be ours continue to buy infringing Japanese products, with blatant disregard for our patents. These lost revenues will never be recaptured.

In conclusion, Mr. Chairman, we believe we have amply demonstrated that the Japanese patent system provides a significant non-tariff barrier to the penetration of the Japanese high-technology market by U.S. firms.

We agree with you, Senator D'Amato; free trade must be fair trade -- and demanding that the Japanese correct their patent system is one important step forward.

We appreciate your interest and attention, and would be pleased to answer any questions you may have regarding this testimony.

American Chemical Society

OFFICE OF THE
PRESIDENT

Ellis K. Fields
President-Elect, 1984
President, 1985
Immediate Past President, 1986

Amoco Chemicals Corporation
Exploratory Research
Post Office Box 400
Naperville, Illinois 60566—D-2
(312) 420-5433
(312) 420-5300

November 21, 1985

The Honorable Charles McC. Mathias
Chairman
Subcommittee on Patents, Copyrights
& Trademarks
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Senator McC. Mathias:

The American Chemical Society (ACS) supports passage of S.1543 and H.R.1069, the "Process Patent Amendment of 1985." These bills would establish a U.S. patent owner's infringement rights against imported goods manufactured by a U.S. patented process.

S.1543 and H.R.1069 would eliminate a longstanding loophole in U.S. patent law by broadening the definition of patent infringement to cover the acts of importing into the United States, or using or selling in the United States, a product produced in another country by a process patented in this country. This change would prevent U.S. competitors from avoiding a patent merely by moving offshore to do their manufacturing. The ACS believes that when U.S. process patent owners are protected from offshore competition, they will have more incentive to invest in research and development. Also, they will be more likely to manufacture in the U.S., thus creating jobs and stimulating the economy. To be competitive in world markets, the U.S. must provide greater incentives for American firms to invest in research, development, and commercialization of its own technology.

Though in support of the legislation, the Society does wish to comment on the following specific provisions of the proposed bills:

PRESUMPTION PROVISION

The "presumption" provision, Section 5 of H.R.1069, is necessary to provide adequate protection for process patents. A process patent owner may not be able to satisfy the burden of proof requirement if forced to prove, by a preponderance of the evidence, that an imported article was manufactured by the patented process.

An example of an industry that is particularly in need of the presumption protection is the biotechnology industry. Often the only protection available to this emerging industry is a process patent. In a typical infringement case, if a U.S. court is to disclose information concerning the process by which a product is made, in certain countries it is illegal for

the foreign manufacturer to disclose this information because it is classified as a "trade secret." When such information falls under the country's trade secret laws, according to the traditional conflict of laws' provision that a potential criminal sanction will prevail against any civil interest, the U.S. biotechnology process patent owner will be unable to obtain the necessary information to satisfy the burden of proof requirement and probably will lose the case.

The American Chemical Society believes that the process patent owner should be protected by including a provision in the law that the product will be presumed to have been made by a patented process if the patent owner has tried without success to determine the process actually used was the patented process, and the court finds a substantial likelihood that the product was produced by the patented process. The foreign manufacturer then would have the burden of proving that the product was not produced by the process patent.

GRANDFATHER PROVISION

The "grandfather" provision, Section 3 of S.1543, which exempts certain existing supply arrangements from the coverage of the bill, is equitable. The intent of this legislation is to provide protection for new ventures in the U.S., not to interfere with old or existing commercial production.

REPORTING PROVISION

The annual reporting requirement, in Section 4 of S.1543, is administratively burdensome and unnecessary. This provision appears incompatible with current interest in federal agency paperwork and budget reduction considerations.

In conclusion, the American Chemical Society, a nonprofit, scientific and educational organization with a membership of over 135,000 chemists and chemical engineers, supports both process patent protection bills. The ACS strongly favors passage of legislation embodying the provisions of H.R.1069 in combination with Section 3 of S.1543. The Society appreciates the opportunity to express support for this legislation and wishes to provide whatever assistance possible to Congress in consideration of this important issue.

Sincerely yours,

Ellis K. Fields

cc: Members, Senate Subcommittee on Patents,
Copyrights, & Trademarks

KSU
KANSAS STATE UNIVERSITY

Kansas State University Research Foundation

Office of the Executive Vice President
Fairchild Hall
Manhattan, Kansas 66506
913-532-5720

Nov. 21, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman
Senate Judiciary Subcommittee on
Patents, Copyrights and Trademarks
Washington, DC 20510

Dear Senator Mathias:

The Kansas State University Research Foundation is the arm of the University charged with managing its patent holdings; therefore, we are very interested in the progress of Senate Bill 1543 entitled "Process Patent Amendment of 1985." We very much favor this legislation for we believe that it will make a much more equitable situation when this Process Patent loophole is plugged.

As a patent attorney myself, I have been well aware of the apparent second class status of the U.S. Process Patent in comparison with a like U.S. Product Patent. This proposed legislation should go far in attempting to potentially correct the disparagement between these supposedly equal patents.

We will be looking forward to hearing of the progress of Senate Bill 1543 and trust that if the bill is amended you will be kind enough to forward a revised copy to us.

The patent community appreciates your untiring efforts in our behalf.

Very truly yours,

John O. Mingle, Esq.
Patent Counsel
Executive Vice President

JOM/mb

PRESIDENT
BIRGIT E. MORRIS
RCA CORPORATION
CN 5312
PRINCETON, NJ. 08540-0028
(609) 734-3249

PRESIDENT-ELECT
TIMOTHY G. ROTHWELL
SANDOZ, INC.
59 ROUTE 10
E. HANOVER, NJ 07936
(201) 386-8762

1ST VICE-PRESIDENT
RAYMOND M. SPEER
MERCK & CO., INC.
P.O. BOX 2000
RAHWAY, NJ 07065-0907
(201) 574-4481

2ND VICE-PRESIDENT
DAVID A. DRAEGERT
THE BOC GROUP, INC.
85 CHESTNUT RIDGE RD.
MONTVALE, NJ 07645
(201) 573-0800 EXT. 272

NEW JERSEY
PATENT LAW ASSOCIATION

P.O. BOX 236, FLORHAM PARK, NJ 07932-0236

SECRETARY
ARTHUR J. PLANTAMURA
ALLIED CORPORATION
P.O. BOX 2245R
MORRISTOWN, NJ 07960
(201) 455-3781

TREASURER
MARTHA G. PUGH
MATHEWS, WOODBRIDGE, GOEBEL,
PUGH AND COLLINS, P.A.
P.O. BOX 1123M
MORRISTOWN, NJ 07960
(201) 267-3444

PAST-PRESIDENT
NCPLA REPRESENTATIVE
PHILIP SPERBER
REFAC TECHNOLOGY
DEVELOPMENT CORPORATION
122 EAST 42ND STREET
NEW YORK, NY 10168
(212) 687-4741

November 21, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman, Judiciary Subcommittee on
Patents, Copyrights & Trademarks
United States Senate
Washington, DC 20510

Re: S. 1543, Process Patent Bill

Dear Senator Mathias:

The New Jersey Patent Law Association supports this legislation, which would give the owner of a process patented in the U.S. the right to bring suit for patent infringement against a party who uses or sells within, or imports into, the U.S. a product that is manufactured by using the process. We also urge you to amend the bill to include a provision that places on the alleged infringer, in certain cases, the burden of establishing that the product was not produced by the patented process. Such a provision appears in H.R. 1069.

We support the legislation for the following reasons:

1) The ability to enforce U.S. process patents will encourage U.S. companies to increase their investment in R&D.

2) The legislation would put U.S. patent law in substantial conformity (in the area of process patent protection) with the patent laws of other industrialized nations, such as Japan, France, the U.K., and West Germany.

3) The ability to enforce U.S. process patents against importers will reduce the incentive for offshore manufacturing, thus preserving U.S. jobs and reducing the trade deficit.

4) The present remedy of U.S. process patent owners - an ITC proceeding under the Tariff Act - is inadequate, because the proceedings are expensive and uncertain, the patent owner cannot obtain damages from the ITC, and relief granted by the ITC can be abrogated by the President.

The amendment regarding reversal of the burden of proof is important, because it is often impossible for a patent owner to obtain the necessary discovery in a foreign country.

Very truly yours,

Birgit E. Morris

Birgit E. Morris
President

P. S. The opinions expressed in this letter are those of the Association and not necessarily those of the employers of the members.

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

ALBERT D. BOURLAND
VICE PRESIDENT
CONGRESSIONAL RELATIONS

1615 H STREET, N.W.
WASHINGTON, D.C. 20062
202/463-5600

November 22, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman
Subcommittee on Patents, Copyrights
and Trademarks
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

The U. S. Chamber of Commerce offers this statement in support of S. 1543, the Process Patent Amendment of 1985.

The Chamber recognizes the unique worth of the U. S. patent system and urges any improvements which will assure its continuing benefit to inventors, industry, government, and the public in general. In order to serve those interests equitably and effectively, the Chamber endorses S. 1543, which would protect patent owners from importation into the United States of goods made abroad by the use of a U. S. patented process.

Our major trading partners, including Japan, West Germany, France, and the United Kingdom, already have provisions similar to S. 1543 in their domestic patent laws. Process patent protection is especially important to protect new, high-technology industries, such as biotechnology. In the biotechnology field, a process patent often is the only protection available for inventions.

Although relief for process patent owners is available from the U. S. International Trade Commission (ITC) in certain circumstances, that remedy often is inadequate. Even if pending legislation should be enacted to strengthen the remedies available for patent, trademark and copyright owners before the ITC, enactment of S. 1543 still is needed to ensure complete relief, including monetary damages.

S. 1543 contains a safeguard to protect the legitimate interests of retailers who market imported products. Under the bill, retailers and other purchasers are not held liable for patent infringement unless they know of or are notified of infringement. Moreover, retailers are protected by hold-harmless clauses in contracts with their suppliers and by a section of the Uniform Commercial Code which provides buyers with a warranty against claims of patent and trademark infringement. In the case of product patents, retailers have operated under these rules for many years without problems. There is no reason to believe the situation would be any different in the case of process patents.

We respectfully request you to include our comments in the hearing record. Thank you for the opportunity to present our views.

Sincerely,

A D Bourland

Albert D. Bourland

ALLEGHENY LUDLUM STEEL CORPORATION

RICHARD K. PITLER, PH.D.
SENIOR VICE PRESIDENT AND TECHNICAL DIRECTOR

RESEARCH CENTER
ALABAMA & PACIFIC AVENUES
BRACKENRIDGE, PENNSYLVANIA 15014
412-226-2000
TELEX NO. 866444

November 25, 1985

The Honorable Charles McC. Mathias, Jr.
Chairman, Judiciary Subcommittee on
Patents, Copyrights & Trademarks
United States Senate
Washington, D.C. 20510

Re: Process Patent Legislation S.1543

Dear Senator Mathias:

On behalf of Allegheny Ludlum Steel Corporation, I am writing to advise you that we strongly support S.1543 and that such process patent legislation should be enacted without delay. Under such a bill, it would be infringement of a U.S. process patent to import, use, or sell in the United States a product produced in another country by a process which is patented in this country.

Such legislation would provide parity with the patent laws of other industrialized countries which do not permit evasion of process patent owners' rights. Major trading countries, including Japan, West Germany, France, and the United Kingdom, have similar provisions in their laws. Furthermore, the European Patent Convention, which has ten member countries, provides that the protection conferred by the patent to the process shall extend to the products directly obtained by such a process. The legislation does no more than U.S. trading partners have already done in their patent laws to protect against foreign piracy of patented processes.

The only remedy currently available to U.S. process patent owners is in the form of an exclusion order from the U.S. International Trade Commission under Section 337 of the Tariff Act. There are deficiencies of the ITC proceeding, such as the special economic impact requirements and the lack of any damage remedy, which seriously reduce its effectiveness. Furthermore, attorneys' fees are unavailable from the ITC and an Executive Order of exclusion must be obtained and may not be obtainable from the President for policy reasons. Although importation of a product made by using a process covered by a U.S. Patent is already recognized as an unfair act of trade, the present U.S. Patent Law must be changed to eliminate practices which unfairly undercut American inventors' rights and which promote unfair foreign competition in domestic U.S. markets.

ALLEGHENY LUDLUM STEEL CORPORATION

The steel industry, of which Allegheny Ludlum is one of the largest specialty steel producers, has been particularly hard hit by foreign imports. To allow foreign producers the free use of our patented research and development results in a travesty. For an industry which has had severe loss of jobs and numerous plant closings, an amendment to the U.S. Patent Law should be enacted which would provide at least as much protection for U.S. industry developed manufacturing processes in the United States as other countries provide to their industries. Clearly, as you have learned from recent hearings, there is wide-spread support for legislation to stop damage to U.S. industries from this form of unfair competition by importation.

We do take exception, however, to Section 3 of S.1543 which is a "grandfather clause" which exempts certain existing supply arrangements from the coverage of the Bill. Particularly, the clause permits the continued use, sale, or importation of products "already in substantial and continuous commercial production on July 31, 1985, or for which substantial preparation for production was made before that date, to the extent equitable for the protection of investments made or business commenced before that date." There is no reason to allow foreign manufacturers, who are taking unfair advantage of the R&D investments of U.S. process patent owners, to be allowed to continue to do so.

We urge the Subcommittee to approve S.1543 without the "grandfather" clause, or a modified version thereof, as soon as possible.

Very truly yours,

R.K. Pitler
Senior Vice President and
Technical Director

RKP:mac
cc:The Honorable Paul Laxalt
The Honorable Orrin G. Hatch
The Honorable Alan K. Simpson
The Honorable Howard M. Metzenbaum
The Honorable Dennis DeConcini
The Honorable Patrick J. Leahy
The Honorable John Heinz
The Honorable Arlen Specter
Mr. R.P. Simmons
P.J. Viccaro, Esq.

Jack R. Halvorsen, President
Illinois Tool Works Inc
8501 West Higgins Road
Chicago, Illinois 60631-2887

The Patent Law Association of Chicago

1985 Officers

Jack R. Halvorsen
President
Theodore W. Anderson
First Vice President
Paul C. Flattery
Second Vice President
William M. Lee, Jr.
Secretary
Patrick D. Ertel
Treasurer

Board of Managers

Davis Chin
Robert F. I. Conti
Francis A. Even
Sidney N. Fox
Raymond I. Geraldson, Jr.
Allan J. Hoover
John T. Lanahan
Joyce R. Niblack
Robert L. Zieg

November 26, 1985

The Honorable Charles McC. Mathias
387 Russell Office Bldg.
Constitution Avenue
Washington, D.C. 20510

Dear Senator Mathias:

The Patent Law Association of Chicago, the oldest of the patent law groups, strongly supports the enactment of Senate Bill S.1543 to provide badly needed protection to process patentees.

We strongly urge that this bill be modified to include specific language relating to the presumption that the imported product was made using the patented process as found in H.R. 1069 (proposed new Section 295 to Title 35).

Secondly, we recommend the deletion of the second sentence of Sec. 3 which starts "This Act shall not abridge...." and continues through "....commenced before that date." It is felt that this leaves too wide a loop hole for evasion of the intent of the proposed legislation. It does nothing for the "legitimate" generic drug operation.

Our association supports this legislation as a necessary tool to be available to the process patent holder as an appropriate remedy against the pirates of the world, both foreign and domestic.

Sincerely,

Jack R. Halvorsen, President
The Patent Law Association of
Chicago

JRH:baj

K MART CORPORATION
INTERNATIONAL HEADQUARTERS
3100 WEST BIG BEAVER RD.
TROY, MICHIGAN 48084

December 23, 1985

The Honorable Charles McC. Mathias
United States Senate
Washington, D.C. 20510

Re: S 1543 - "Process Patent" Legislation

Dear Senator Mathias:

"Process patent bills" purport to provide greater protection for industrial property owners and for consumers. In fact, however S 1543, would severely impinge upon general merchandise retailers who sell tens of thousands different products, involving literally hundreds of thousands and millions of "processes" in their component makeup. In putting liability on the retail seller of a product there is no practical means for most retail sellers to know what processes are involved or what patents cover these processes.

S 1543 and similar bills regarding "process patent protection" would provide a damages cause of action for sale of merchandise alleged to be protected by process patent from the point or date where an innocent retailer "knew of or was notified of the infringement."

This is a highly prejudicial provision because millions of "processes" lie hidden behind the manufacture of a product and are not notated on such products (and are therefore unknowable to retailers and consumers):*

(1) If a process patent infringement claim is indeed proven by a claimant in court, then infringement damages ought to run forward from point or date only of an intentional re-order or new purchase of merchandise product(s) subject to the claim [merchandise on hand, purchased by an innocent retailer prior to notice of an adjudication of a patent infringement, should be allowed to be sold out at retail by the innocent purchaser-retailer until such previously-ordered stock is exhausted, without penalty of damages to the retailer], and

(2) written notice, by Certified Mail addressed to a retailer's officer(s) should be required for notice of infringement adjudication(s).

If you or your staff colleagues have any question, or a need for more specific information, please feel free to let me know.

Sincerely,

A. ROBERT STEVENSON

JCT:ds

(*) Unlike product patents, where an interested party can search, it would by literally impossible for a retailer to search for relevant process patents behind each product in which it deals.

American Bar Association

March 10, 1986

The Honorable Charles McC. Mathias
Chairman of Subcommittee on Patents, Trademarks
& Copyrights
Senate Judiciary Committee
Dirksen Senate Office Building
Washington, D.C. 20510

SUBJECT: Mathias Bill S.1543
Process Patent Amendment

Dear Mr. Chairman:

This is to provide you with the position of the American Bar Association as it relates to the above-identified patent legislation. The position conforms to policy that has been approved and adopted recently by the ABA House of Delegates.

The ABA supports the process patent amendment legislation in principle. However, since several Subcommittee Staff working drafts have been generated after the introduction of S.1543, it is necessary that we address specific points which have been raised either in the Bill as originally introduced or in one or more of the drafts.

(1) We have no position on the use, or absence thereof, of the term "directly" when used in the sense of the patent owner being granted the right to exclude others from practicing products "directly produced" according to the patented process.

(2) We do not favor the definition for "notice of infringement" as it appears in the latest Staff Draft. Such definition should not differ from, or be in variance with, the definition for "notice" which now exists in 35 USC 287 of the Patent Law. The present long-standing statutory definition should be continued as a single definition for purpose of clarity, for continuity in the law, and because it has withstood the test of time.

Accordingly, we recommend that such definition be revised to read as follows:

> "'Notice of infringement' means the infringer was notified that a product was produced by a patented process without authorization of the patentee. Filing of an action for infringement shall constitute such notice.".

CHAIRMAN
J. Jon Jancin, Jr.
7815 Fulbright Ct.
Bethesda, MD 20817
703/769-2401

CHAIRMAN-ELECT
William Marshall Lee
Ste. 3550
150 S. Wacker Dr.
Chicago, IL 60606
312/726-1982

VICE-CHAIRMAN
John K. Williams
2001 Ferry Bldg.
San Francisco, CA 94111
415/473-4150

SECRETARY
Ronald B. Coolley
Ste. 4200
20 N. Wacker Dr.
Chicago, IL 60606
312/621-1300

FINANCIAL OFFICER
Joseph J. Previto
Empire State Bldg.
New York, NY 10001
212/736-2080

SECTION DELEGATE TO THE HOUSE OF DELEGATES
William E. Schuyler, Jr.
Ste. 400
4801 Massachusetts Ave. NW
Washington, DC 20016
202/966-0086

DEPUTY SECTION DELEGATE TO THE HOUSE OF DELEGATES
Morton David Goldberg
36th Flr.
1185 Ave. of the Americas
New York, NY 10036
212/575-6150

ASSISTANT TO THE SECRETARY
Roger Norman Coe
Miles Labs, P.O. Box 40
Elkhart, IN 46515
219/262-7937

ANNUAL PUBLICATIONS EDITOR
Mark T. Basinow
125 S. Wacker Dr.
Chicago, IL 60606
312/372-2160

NEWSLETTER EDITOR
Zachary S. Fisz
2606 Spencer Rd.
Chevy Chase, MD 20815
301/986-6380

COUNCIL MEMBERS

LAST RETIRING CHAIRMAN
Rudolph J. Anderson, Jr.
Monsanto Co.
800 N. Lindbergh Blvd.
St. Louis, MO 63167
314/694-3714

William H. Elliott, Jr. (1986)
Ste. 3131
12 S. 12th St.
Philadelphia, PA 19107

Daniel D. Fetterley (1989)
Ste. 1102
735 N. Water St.
Milwaukee, WI 53202

Edward G. Fiorito (1989)
Dresser Industries
1505 Elm St.
Dallas, TX 75201

[illegible] (1988)
606 Third Ave.
New York, NY 10156

Jack C. Goldstein (1988)
P.O. Box 4433
Houston, TX 77210

Michael K. Kirk (1988)
5641 River Dr.
Lorton, VA 22079

I. Fred Koenigsberg (1987)
ASCAP
One Lincoln Plaza
New York, NY 10023

Henry F. Meinbeck, Jr. (1989)
G.E. Co.
3135 Easton Turnpike
Fairfield, CT 06431

John E. Maurer (1987)
5040 Monsanto International Personnel
800 N. Lindbergh Blvd.
St. Louis, MO 63167

Peter F. Nolan (1989)
Walt Disney Productions
500 S. Buena Vista St.
Burbank, CA 91521

Albert Robin (1987)
330 Madison Ave.
New York, NY 10017

Thomas E. Smith (1988)
Ste. 950, 150 S. Wacker Dr.
Chicago, IL 60606

BOARD OF GOVERNORS LIAISON
Edward B. Winn
3330 Republic Bank Bldg.
Dallas, TX 75201

STAFF LIAISON
Michele A. Kukowski
American Bar Center
750 N. Lake Shore Drive
Chicago, IL 60611
312/988-5595

(3) We believe that the proposed legislation should further provide a "limitation of damages" similar to that now in 35 USC 287 --- i.e., that no damages for infringement can be recovered based on use, sale or importation, as set forth in the proposed legislation, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages would be recovered only for infringement occurring after such notice.

(4) We do not object to the concept of rebuttable presumption as to foreign manufacture.

(5) However, we do object to rebuttable presumption as applicable to domestic manufacture and to litigants subject to 28 USC 1400(b).

(6) Further, we recommend deletion of any provision in the rebuttable presumption concept which shifts the burden of proof from the plaintiff to the defendant, in a patent infringement suit, whenever the Court finds that there is a presumption of a product having been produced according to a patented process. On the other hand, we would not be opposed to a provision that would shift the burden of going forward with the evidence upon a Court's finding of rebuttable presumption.

Comment on Rebuttable Presumption: It is generally understood that the scope of the proposed legislation has been extended because of a perceived GATT Treaty related problem --- i.e., that the proposed legislation has been broadened from, at first, simply providing relief in a purely foreign export situation to, now, revising our laws as applicable to patent related events that take place within or outside of the United States.

Referring to the latest Staff Draft of the proposed legislation, the rebuttable presumption provision therein would permit shifting the burden of proof in a patent infringement case even onto a defendant located in the United States, or even onto a person subject to the jurisdiction of a U.S. District Court.

Since discovery is available in the United States as to such defendants, rebuttable presumption in such situations is not necessary. The concept as proposed goes beyond the District Court practice that now applies to parties in patent litigation --- and, accordingly, is undesirable.

(7) It is for such reason that we object to the form of rebuttable presumption presented in the most recent Staff Draft.

(8) It is also for such reason why we recommend that rebuttable presumption not apply whenever, at the time of commencement of a patent infringement action, the manufacturer of the product produced by the patented process is either:

(a) Subject to the jurisdiction of a U.S. District Court in which venue as to such manufacturer can be established under 28 USC 1400(b); or

(b) Consents to such jurisdiction in the District Court in which the action has been brought.

(9) I have one final matter to bring to your attention without specific recommendation since the ABA has not had the time to review this matter because it was proposed only recently in a Draft Revision to read as follows:

"Damages for infringement occurring after notice of infringement with respect to a unit of the product that was received by the infringer before notice of infringement shall be limited to a reasonable royalty upon each such unit.".

Previously, the term "purchased" was used in place of the word "received". The earlier term appears to fit more closely to the spirit of the intended equitable provision in the legislation's "Grandfather" Clause.

It is also possibly pertinent to point out that use of the term "purchased" appears to better track a similar provision in the recently enacted Semiconductor Chip Protection Act where the innocent infringement provision talks to an infringing semiconductor chip product "purchased before having notice of protection....". See 17 USC 907(c).

We sincerely appreciate this opportunity to comment upon legislation that we support in principle, and whose enactment we favor, with the revisions recommended herein.

Please call upon me for any additional information or assistance that you believe the ABA can provide regarding the subject legislation.

Very truly yours,

J. Jancin, Jr.
Section Chairman

American Bar Association

SECRETARY
William H. Neukom
3500 First Interstate Center
Seattle, WA 98104

WRITER'S DIRECT LINE

312/988-5152

March 15, 1986

Honorable Charles McC. Mathias
Chairman, Subcommittee on Patents,
Copyrights and Trademarks
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

RE: Process Patent Protection

Dear Mr. Chairman:

At the meeting of the House of Delegates of the American Bar Association held February 10-11, 1986, the attached resolution was adopted upon recommendation of the Section on Patent, Trademark and Copyright Law. The action taken thus becomes the official policy of the Association in this matter.

This resolution is transmitted for your information and whatever action you may deem appropriate. If hearings are scheduled on the subject of this resolution we would appreciate your advising Robert D. Evans, Director of the American Bar Association Governmental Affairs Group, 1800 M Street, N.W., Washington, D.C. 20036, 202/331-2214.

Please do not hesitate to let us know if you need any further information, have any questions or if we can be of any assistance.

Sincerely yours,

William H. Neukom

WHN:det
Attachment
1619f/8924k

cc: J. Jan Jancin, Jr., Chairman
Section on Patent, Trademark
and Copyright Law
Robert D. Evans, Esquire
Mmes. Barbara H. Jarr
Michele A. Kukowski

750 NORTH LAKE SHORE DRIVE, CHICAGO, ILLINOIS 60611
TELEPHONE (312) 988-5000

REPORT NO. 122

BE IT RESOLVED, That the American Bar Association:

A. Supports in principle the enactment of legislation which (a) would establish that whoever without authority uses or sells within, or imports into, the United States during the term of a United States process patent a product produced by such patented process, infringes the process patent, and (b) would create a rebuttable presumption, in actions based on such use, sale, or importation, that a product was produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has exhausted all reasonably available means through discovery or otherwise but had been unable to determine, from information provided by the manufacturer of the product, the process actually used in the production of the product; provided, however, that the legislation shall further provide that (i) no damages for infringement shall be recovered based on such use, sale or importation except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages shall be recovered only for infringement occurring after such notice, and (ii) the rebuttable presumption shall not apply if, at the time of commencement of the action, the manufacturer of the product produced by the patented process is either subject to the jurisdiction of a United States District Court in which venue as to such manufacturer can be established under 28 U.S.C. §1400(b), or consents to such jurisdiction in the District Court in which the action has been brought;

B. Supports H.R. 1069 (Moorhead, 99th Congress, 1st Session) or similar legislation, if the rebuttable presumption established in Sec. 5 thereof is qualified as recommended above; and

C. Modifies its previous position, adopted in August, 1984, on the "National Productivity and Innovation Act" -- S. 1841 and H.R. 3878 (98th Congress) -- to the extent it is inconsistent with paragraphs A and B above -- specifically by deleting (d) of that resolution.

5613f/25
February, 1986